

# EUROPEAN HOSPITAL

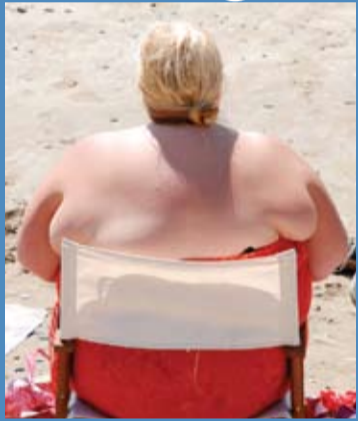
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VOL 19 ISSUE 3/10

JUNE/JULY 2010

## Weight loss = cash gain



**United Kingdom** – Sometimes spending money to save it works – sometimes not. It was argued, for example, that paying some immigrants £2,000 to return to their homelands, rather than remain as social and economic burdens, would only encourage more to come for the pay-off. The National Institute for Clinical Excellence (NICE) met recently to discuss the use of cash incentives in health, which have included offers of monetary rewards for addicts who stay off drugs, £10 CD vouchers to youngsters who take a Chlamydia test, and cash up to £425 for obese people who lose weight.

A trial of the latter was launched by the National Health Service (NHS) at a primary care trust in January 2009. Called Pounds for Pounds (the word for the £ as well as lb weight).

402 volunteers agreed to reduce their weight over a 12-month period. In that year, 100 of them lost on average 25lbs each. What happened to the other 300 people? They failed to reach weight-loss targets and did not complete the course.

Noting the high drop-out rates, Claire Martin, Acting Assistant Director of Public Health for NHS Eastern and Coastal Kent PCT, said: 'It's very difficult to interpret the results to show how successful this would be across our population.'

At the leading charity Diabetes UK, Policy Manager, Gavin Terry, concluded that cash incentives may appeal to some, but: 'We need to incentivise a healthy, happy and active lifestyle as a sustainable end result, rather than a cash payout.'

*Diabetes reports – Pages 21-24*

# Evaluating US health reform

**'The government has no authority to compel citizens to buy private goods – including private health insurance'**

On the first day of the German Capital Congress, expert observers of USA's American health policy reform discussed whether the US health reform can be considered a milestone on the way to a socially-responsible state.

The discussion, led by Professor Reinhard Busse, Chair for management in healthcare at the TU Berlin and a Director of the European Observatory on Health Systems and Policies, included John C Kornblum, former US ambassador in Berlin, and Jack Warren Salmon, Professor for Health Policy and Administration at the University of Illinois.

John C. Kornblum adamantly rejected the suggestion that the healthcare reform adopted in Washington in March 2010 can



From left: Jack Salmon, John Kornblum, Reinhard Busse

be interpreted as a milestone on the way to a socially responsible state. He pointed out that the USA is not a State in the German sense of the word. Rather, US citizens see themselves as people and the government as mere administration, as can be seen in that choice of word for government. Self-determination is the most important thing for US citizens. 'They already

see a general health insurance as a significant, dangerous, and irreversible step on the way to socialism,' he declared. This explains the fierce opposition to the reform, especially among Republicans. The reform project did not originate in the desire to transform the USA into a socially responsible state, but out of a necessity to save money.

## Doctors' shifts and patient safety raises concern

**United Kingdom** – The reduction in junior doctors' hours to 48 hours a week with the introduction of the European Working Time Directive (EWTD) has increased the number of work shifts and continuity of care is suffering as patients are 'handed over' again and again to different doctors, according to the Royal College of Physicians (RCP).

After receiving anecdotal reports of problems relating to handover practice, in March this year the RCP launched a survey to seek doctors' experiences in this respect and lead to initiatives to improve the handover situation for the benefit of all concerned.

The initial results from the 3-week long survey, presented at a meeting in May, revealed examples of good and bad handover practice in British hospitals and also that there was no consistent standard for handovers.

As Improving Working Lives Officer for the RCP's Medical Workforce Unit, Dr Jean McEwan is involved with areas of gender balance, flexible working and improving the work/life balance within the medical profession. Based at the Royal Free and University College London Medical School, the UCLH, NHS Foundation Trust and the Heart Hospital, Dr McEwan is a Reader in Cardiology, an Honorary Consultant Cardiologist and Director of Clinical Teaching.

The college is now analysing these early results as it moves forward in its efforts to improve handover practice and find solutions.

Cardiologist Dr Jean McEwan, the RCP's Improving Working Lives Officer and project leader of the handover study, said the aim was to gain three things: to understand what current handover practice is within hospitals; to understand the challenges that doctors feel they face when trying to implement good

handover practice, and to gather examples of how pioneers of the work on handover are trying to solve the problem. 'When trying to assist doctors in implementing good handover we had no clear idea of what is currently in place and the challenges currently faced in trying to implement good handover practice,' she explained. 'The survey was necessary to garner this information and to ensure that work by the RCP is as beneficial as it can be for patients and doctors.'

All consultants who participate in the RCP consultant census and all trainees registered with the Joint Royal Colleges Postgraduate Training Board (JRCPTB) – in total 7,417 doctors – were invited to take part.

While acknowledging this represents a subset of all doctors, the RCP believe that opinions gathered in this group are likely to indicate some problems that are universal. In a future stage of the handover project, the college will pursue a multidisciplinary input.

*continued on page 2*

Professor Busse pointed out that amazing amounts of public money in the USA are channelled into the health system, almost as much as in Germany in terms of proportion of gross domestic product (GDP). German public health expenditure amounts to about 8% of GDP. 'The difference between the USA and Germany is the fact that on top of the public funds in the USA another 8% of private health expenditures are spent compared to only 2.5% here,' he pointed out. Citing a McKinsey study he added that the USA has technically the most efficient healthcare system in the world; the level of service for individuals, however, is relatively low and there are fewer physicians and hospital beds compared to Europe. The discrepancy between high expenditure levels and low service levels, he added, is due to the use of the most innovative medical equipment for which usually far more money is charged per treatment than in Europe. This has often led to the misunderstanding that, in the USA, little money is spent on healthcare. The opposite is true. The reform is intended to assure that the money is spent more efficiently, for the benefit of – nearly everyone.

Professor Salmon, who has worked in the healthcare sector since 1964, welcomed the adoption of the healthcare reform by the Democrats, as did all members on the panel. However, he emphasised that this legislation is so complex, with its nearly 3,000 pages, that it is difficult for him, even as a professional, to grasp immediately the meaning and scope of the individual clauses.

The reform intends that, by 2019, half of the USA's 50 million citizens currently uninsured will be insured. They can compare and ultimately purchase an insurance policy from among a total of 15,000 private insurers through a 'health insurance exchange' in their respective State. Unlike today, low-income

*continued on page 2*

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# EUROPEAN HOSPITAL Reader Survey

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#### 1. SPECIFY THE TYPE OF INSTITUTION IN WHICH YOU WORK

General hospital  Outpatient clinic  University hospital

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#### 2. YOUR JOB

Director of administration  Chief medical director  Technical director

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Medical practitioner/type \_\_\_\_\_  
Other/department \_\_\_\_\_

#### 3. HOW MANY BEDS DOES YOUR HOSPITAL PROVIDE

Up to 150  151-500  501-1000  more than 1000  
 None, (not a hospital/clinic)

#### 4. WHAT SUBJECTS INTEREST YOU IN YOUR WORK?

Surgical innovations/surgical equipment  Radiology, imaging/high tech advances  
 Clinical research/treatments/equipment  Intensive Care Units/management/equipment  
 Ambulance and rescue equipment  Pharmaceutical news  
 Physiotherapy updates/equipment  Speech therapy/aids  
 Nursing: new aids/techniques  Laboratory equipment, refrigeration, etc.  
 Hospital furnishings: beds, lights, etc.  Hospital clothing and protective wear  
 Hygiene & sterilisation  Nutrition and kitchen supplies  
 Linens & laundry  Waste management  
 Information technology & digital communications  Hospital planning/logistics  
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Other information requirements - please list \_\_\_\_\_

#### ESPECIALLY FOR DOCTORS:

Please complete the above questions and we would like you to answer the following additional questions by ticking yes or no or filling in the lines as appropriate.

What is your speciality? \_\_\_\_\_

In which department do you work? \_\_\_\_\_

Are you head of the department?  Yes  No

Are you in charge of your department's budget?  Yes  No

How much influence do you have on purchasing decisions?

I can only present an opinion  Yes  No

I tell the purchasing department what we need  Yes  No

I can purchase from manufacturers directly  Yes  No

Do you consider that your equipment is out-dated  Yes  No

relatively modern  Yes  No

state-of-the-art  Yes  No

Do you use/buy second-hand equipment?  Yes  No

If so, what do you use of this kind? \_\_\_\_\_

Is your department linked to an internal computer network?  Yes  No

Is your department linked to an external computer network?  Yes  No

Is your department involved with telemedicine in the community?  Yes  No

Do you consider your department is under-staffed?  Yes  No

Are you given ample opportunities to up-date knowledge?  Yes  No

Do you attend congresses or similar meetings for your speciality?  Yes  No

This information will be used only in an analysis for European Hospital, Theodor-Althoff-Str. 39, 45133 Essen, Germany, and for the mailing out of future issues and the EH electronic newsletter. EH 3/10

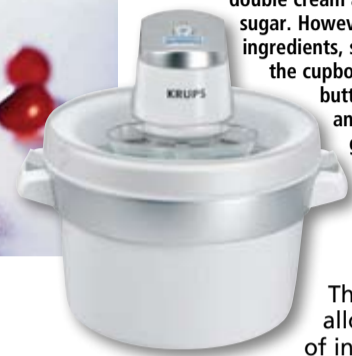
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# Your chance to win a Krups ice cream maker



It's summer.  
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Imagine: With the Krups GVS2 you could make unusual choices. One colleague loves combining beetroot and orange, another ginger and butternut squash, while another produces a keen Margarita ice cream by mixing tequila, lime juice, double cream and icing sugar. However, if stuck for ingredients, she simply raids the cupboard for peanut butter, or marmalade and has even used green tea as an interesting option



The feeder bowl allows the addition of ingredients during operation

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Some believe it was the Italians who invented ice cream in the 17th century. What is known for sure is that French aristocrats were quick to adopt this cream- or custard-based dessert.

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Whatever your personal taste, with our ice-cream maker prize you could create gorgeous homemade ice creams, sorbets or yogurt desserts.

Just use your favourite fruit or an interesting combination for some cool pleasure – not just for you, but family and friends. The Krups instruction booklet also includes excellent recipes, such as iced strawberry soufflé and orange sorbet.

In a hurry? The machine's freezing cylinder is a fast operator – in 30 minutes you'll have a frozen treat.

#### Krups GVS2 features:

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- The transparent locking lid with wide opening allows you to check the ice-cream making process and add ingredients easily.

- A double insulated bowl provides quick freezing and eliminates the need for salt or ice
- Capacity 1.6 litres (corresponding to one litre of ice cream)

Accessories: a spatula and a flexible preserving lid for the bowl

Design: The control panel and bowl ring are finished in chrome, and the handles are removable for easier storage.

#### Why enter?

It's so easy – and, since we launched our competitions some years ago, winning medical and healthcare workers throughout Europe have been delighted to receive the fine prizes featured in *European Hospital*.

So, don't delay, enter our competition today (why not right now!). Simply go to the EH website. Good luck!

The winner of the Beurer PM 70 watch featured in our competition in EH issue 2/10 and on our website, is:  
**Radiology consultant  
Dr Herbert Wetzler,  
from Roth, Germany**



## Evaluating US health reform

*continued from page 1*

earnings will receive tax relief and the insurers will not be able to reject potential policy holders so easily because of chronic illnesses, impending expensive treatment or other risk factors. Moreover, there will be a penalty if citizens do not do not take out health insurance voluntarily. Prof. Salmon expects such a penalty to be challenged because the federal government does not have the authority to compel citizens to buy private goods, such as a private health insurance. The courts will most likely be asked to confirm the 'right to be free of insurance'.

The professor added that another weakness in the US reform is the fact that an estimated 23 million people will remain uninsured: these include eight million illegal immigrants, people who refuse health insurance for religious reasons, prisoners, and indigenous people. He also regrets that the left wing of the Democratic Party was unable to impose the demand for a so-called

'public option' for health insurance provided by the State. Moreover, he deplored that on the whole the reform does too little to develop infrastructure, such as promoting community health centres.

One of the basic problems of the US healthcare system, in the view of all panellists, appears to be the lack of preventive medicine. General practitioners are underpaid and there are simply too few of them. Hence patients do not present for regular check-ups but end up directly in the emergency room. The reform might change this, since the barrier to regular medical checks will be reduced for the insured.

Success or failure of the healthcare reform will ultimately depend on its gradual implementation. Full implementation is expected by 2019. However, a number of elections will be held before then – the next Congressional elections are scheduled for November this year – and probably a batch of complaints will have to be dealt with as well.

Report: Bettina Döbereiner

## Doctors' shifts...

*continued from page 1*

'We hope the survey will in particular identify whether there are areas where there are no formal arrangements in place for the handover of patients,' Dr McEwan said, adding: 'Further to this, we hope that it will highlight the work that needs to be done in order to ensure that handover provides the benefits that it can for patients and doctors alike.'

The RCP believes there will be long term benefits for patients, doctors and hospitals in effectively addressing the issue.

Along with improving patient safety, care and experience of healthcare, Dr McEwan added that good handover is likely to be effective in reducing the length of in-patient stays, as well as possibly providing educational benefit to those who participate in it.

The RCP and partners are now focusing on the survey data to decide what practical work needs to be done to implement best handover practice in hospitals.

Report: Mark Nicholls

# The sustainable hospital

**Austria** – ‘Sustainability’ is more than a buzz word. The original meaning – to limit the use of natural resources so they will be available for future generations – has been expanded to encompass an economic as well as a social dimension. Companies – including hospitals – are increasingly integrating the concept of sustainability in their corporate strategies. ‘It is our vision that hospitals ensure their own sustainability and at the same time contribute effectively to a sustainable social development,’ says psychiatrist Dr Karl Purzner, head of Organisational Development at Otto-Wagner-Spital in Vienna, who is also a hospital manager. At the hospital an interdisciplinary team of scientists and clinical staff have launched a pilot project called *Sustainable Hospital*. ‘We aim to establish sustainability as an important corporate principle,’ explained Dr Purzner, during a symposium in Vienna.

In the course of the project a so-called Sustainability Balanced Scorecard (SBSC) was developed based on the traditional Balanced Scorecard, an instrument designed to focus corporate management on specific agreed objectives. The idea is to improve the quality of the outcome with key criteria – clinical care, health promotion, profitability, social indicators (stress levels of staff/patients) and ecology (consumption of materials and energy). ‘SBSC’, Purzner is convinced, ‘supports the development efforts in an organisation by focusing on the essentials. In addition it facilitates communication among professions and hierarchy levels.’

‘Key strategy when establishing a sustainable hospital is sustainable demand planning’, says Uli Weisz of the institute for social ecology, University Klagenfurt, who was a partner in the project. Incorrect assignment of hospital beds, he explains, are not necessarily a micro-economic problem in the hospital, but they do cause costs on the social – the macro-economic – level, because they do not deliver positive outcomes but contribute to staff stress and generate unnecessary consumption of resources and emissions.

At Otto-Wagner-Spital, the improvement and resource-saving potential of sustainable demand-based planning was tested in a weaning centre – a pneumonology centre where patients are ventilated according to individual needs in certain ‘step-down’ units. A survey at Otto-Wagner-Spital indicated that the length of stay of ventilated patients in the ICU could have been reduced by 13.5% if the patients had been moved to a Respiratory Care Unit (RCU). Even more: the length of stay in the RCU could have been reduced by 56% because many patients did not need intensive care at all. ‘At the pilot hospital, a three-step weaning centre could save 8% of the costs, which translates into €4.1 million and material savings of 352 tons’, Uli Weisz underlined.

‘We cannot afford to not invest in sustainable development,’ concluded Josef Aumayr, technical director at Otto-Wagner-Spital.

However, beware of the inflationary use of the term sustainability. ‘Unbalanced optimisation of the healthcare system, be it in favour of



BARBARA KROBATH



Uli Weisz



Dr Karl Purzner



Willi Haas



technical or medical feasibility, be it in favour of costs, undoubtedly will create boomerang effects,’ warned Willi Haas of the institute for social ecology, University Klagenfurt. A strong focus on technical and medical solutions opens up capacities that need to be used. Increased efficiency might initially reduce costs but it also leads to increased application and cost increases that can no longer be financed and will require healthcare services to be reduced based on entirely unforeseeable priorities. If that happens, Willi Haas fears ‘sustainable development will be considered a curse rather than an opportunity’.

Report: Michael Krassnitzer

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## Multiple Sclerosis drugs scheme 'a costly failure' : German hospitals fare well despite the economic crisis

**United Kingdom** - A multiple sclerosis risk sharing scheme, set up by the Department of Health (DoH) in 2002 to ensure that disease-modifying drugs were available on the National Health Service (NHS), has been deemed 'a costly failure', according to researchers reporting on [www.bmj.com](http://www.bmj.com) in June. The scheme, they advise, should not be continued.

Estimated to have cost around £50m annually, the researchers point out that, if an assessment had been completed two years after the scheme began, the NHS could by now have saved around £250 million. Only in 2009 – seven years after the scheme was set up – was the first analysis of the data undertaken and, although this revealed that patient outcomes were much worse than predicted, the scheme's scientific advisory group judged that it was premature to reduce prices without further analysis.

Under the terms of the scheme, the government agreed to provide these drugs on the NHS while research was carried out to assess their long term cost effectiveness. The NHS would then gradually stop paying for the drugs if patients did not appear to be benefiting.

Health economist Christopher McCabe, and colleagues at the University of Leeds, argue that none of the reasons for delaying the price review withstand critical assessment. They raise concerns about the independence of the group, which includes representatives from the drug manufacturers, patient groups, clinicians and the DoH. The delay in the publication of the first results is a further cause for concern, they add.

James Raftery, Professor of health technology assessment at Southampton University, supports these concerns and raises further questions about the independence of the advisory group, and the overall governance of the scheme.

The scheme was a success for the drug companies, who sold at close to full price to the NHS, he said. However, for the NHS it can be judged only as 'a costly failure'. According to the professor, 'Monitoring and evaluation of outcomes in future patient access schemes must be independent of the companies involved. Transparency is essential, involving annual reports, access to data, and rights to publish. Any of these might have helped avoid the current fiasco.'

However, Alastair Compston, Professor of Neurology at the University of Cambridge, argued that the scheme has benefited patients, though he acknowledges that its governance was inadequate and that its terms of reference were not delivered. He also warns that attempts to force the drug companies to repay costs would be likely to trigger complex legal arguments.

George Ebers, Professor of Clinical Neurology at the University of Oxford, believes that the outcome measures used in the scheme were flawed. He also says that the scheme's findings raise questions about industrial-academic relationships and their governance. 'The scheme may have been well intentioned, but perhaps the public interest would be served by an independent inquiry.'

Neil Scolding, Professor of Clinical Neurosciences at the University of Bristol and Frenchay Hospital, described the scheme as a clever achievement, which despite being flawed, has had unintended beneficial consequences. He argues that the scheme has spawned an extremely successful infrastructure of specialist MS care in the UK and that the drugs prescribed will have prevented thousands of relapses. He also said: 'It leaves a platform for introducing new treatments and executing clinical research that is second to none in the world.'

## German hospitals fare well despite the economic crisis

In its sixth issue, the *Hospital Rating Report*, first introduced to the public in Berlin during the 2010 Capital City Congress for Medicine and Health, again examined the financial situation of German hospitals.

The study shows financial improvement during 2009 and 2010, despite the economic crisis, but forecasts that it will deteriorate again from 2011. Community hospitals are particularly likely to feel the effects of the high level of debt of their local authorities. Thus further advances in productivity are required; a shake-up in some regions is also feasible. Rural regions particularly need new, economically sustainable kind of healthcare provision – for example, the complete integration of out- and in-patient sectors.

2008 was a difficult year for hospitals, but 2009 and 2010 – despite the economic crisis – could show better results due to revenue growth generated through the Hospital Financing Reform Act (KHVG). Whilst around 16.4% of all hospitals were at an increased risk of insolvency in 2008 and 'in the red', in 2009 this was the case for only 11% of hospitals, with 8% forecasted for 2010. However, after this the financial situation for hospitals is expected to deteriorate again. To prevent a situation where 18% of hospitals could be in the red by 2020, average annual cost reductions of 0.25% through increases in productivity are required.

### More than 1,000 hospitals surveyed

The *Hospital Rating Report 2010* is based on a sample of 713 annual financial reports from 2007 and 2008 and cost and revenue projections for 2010. In total, the annual financial reports cover 1,032 hospitals.

# Mortality rates: success and failure

## Hospitals treating more cardiac and pneumonia cases show fewer deaths

**USA** – If patients suffering acute myocardial infarction, heart failure, or pneumonia are admitted to hospitals that frequently treat these illnesses they are less likely to die, according to research published in the *New England Journal of Medicine*.

Dr Joseph S Ross and colleagues at the Mount Sinai School of Medicine, New York, analysed cross-sectional data from Medicare claims for all fee-for-service beneficiaries admitted to acute care hospitals for these three common conditions between 2004 and 2006. 'Using hierarchical logistic-regression models for each condition, we estimated the change in the odds of death within 30 days associated with an increase of 100 patients in the annual hospital volume.'

Pneumonia patients treated at larger-volume hospitals were 5% less likely to die in the first month than patients treated at hospitals where few cases were handled. The death rate for heart failure was 9% lower for busy hospitals and 11% lower for heart attacks. Generally, teaching hospitals needed fewer patients to attain a lower risk of death.

For each of the three conditions, the association between volume and outcome was reduced as the hospital's volume increased. For

acute myocardial infarction, once the annual volume reached 610 patients (95% confidence interval [CI], 539 to 679), an increase in the hospital volume by 100 patients was no longer significantly associated with reduced odds of death. The volume threshold was 500 patients (95% CI, 433 to 566) for heart failure and 210 patients (95% CI, 142 to 284) for pneumonia.

Understandably, patients who receive surgery, or other procedures, fare better if treated by more experienced doctors. The Mount Sinai study is the first to look at outcomes for common medical conditions.

The researchers calculated, for example, that in a hospital that only treated 17 heart attacks each year, its 30-day death rate could drop by 20% if the hospital treated an additional 100 heart attack patients annually. If it had 70 cases a year to begin with, adding 100 more would result in a 10% reduction.

Adding 100 cases to a hospital that already treats 236 heart attacks would cut the death rate by just 4%. The threshold of improvement was reached once the annual volume hit 610.

Generally, hospitals that had treated the fewest patients with those conditions were the most risky – and hospital size made no difference.

# 360°

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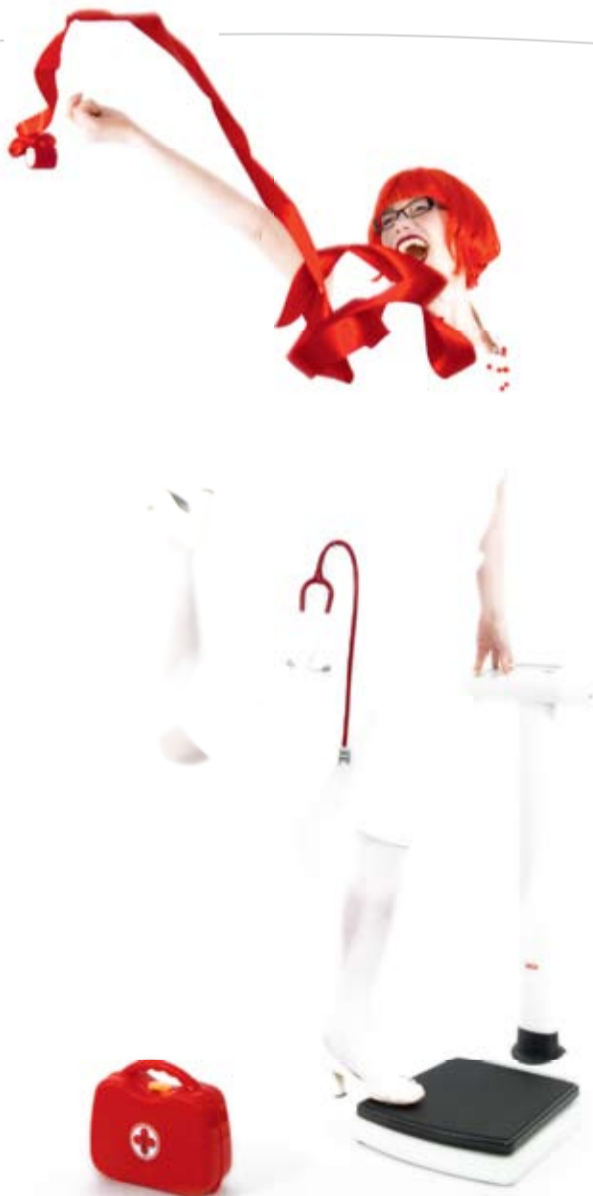


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# LOGISTICS

## Pharmacy storage and retrieval systems save costs

To optimise workflow and save costs in hospital pharmacies automating medication selection is increasingly popular. Since the 1980s, the firm Apostore, based in Gelsenkirchen, Germany, a subsidiary of KHT (Kommissionier- und Handhabungstechnik GmbH), has constantly extended its technological lead in this field of manufacturing, and the company reports that its Carryfix Pusher leads the market in German and Austrian hospital pharmacies.

'This picker works with pushers that sort the goods directly into ward containers after removing them from the shelves lying flat at a depth of one metre,' Apostore explains. 'In this connection, the advantages are obvious: space-saving and consisting of extendable modules, the Carryfix Pushers can automatically place medicines and medical accessories into storage at a speed of 1,500 packages per hour. In total, there is space for up to 100,000 packages on the shelves. At the same time, the storage channels are dynamically assigned and administered. Channels becoming free can therefore be equipped immediately with new, possibly different goods; the maximum picking capacity is 2,500 packages per hour. Merely one to two persons are required for operation of up to 9,000 goods movements with the Carryfix Pusher.'

Goods on pallets or those that cannot automatically be picked (the infusion store and non-medical articles) can be managed and additionally picked with the firm's new paperless picking system as an integral part of the Carryfix Pusher software.

### Optimal coordination

'The scope of supply of the Carryfix Pusher includes materials handling technology e.g. for automatic empty container in-feed, discharge to post-picking sections, cycle starting without dynamic pressure at the checking work station, sorting for delivery tours etc. and naturally also an extensive, individually selectable software package,' Apostore adds. 'In that way, unproblematic connection to all of the existing economic systems of a hospital is ensured. To be particularly emphasised in this case is the direct communication interface BAPI for SAP systems. With this software, the Carryfix Pusher manages all of the goods movements in hospital pharmacies, and/or in the central stores of the hospitals.'

Details (in several languages):  
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## Parkinson's costs

A study to assess the annual average healthcare costs incurred by 486 Parkinson's patients in six countries shows the following results: **Austria:** €19,620, **Germany:** €17,220, **Italy:** €16,680, **Czech Republic:** €11,020, **Portugal:** €5,860, **Russia:** €5,240.

Results from the study, carried out by the European Cooperative Network for Research, Diagnosis and Therapy of Parkinson's Disease (EuroPa), were presented at the European Neurology Congress in June.



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## Wireless communication links medical devices and accessories

Radio Frequency Identification (RFID), a wireless technology primarily known from the field of logistics, has become a focal point in hospitals and similar areas. RFID makes it possible to manage hospital beds from a central location or track the whereabouts of surgical instruments.



RFID simplifies the connection and monitoring of medical accessory components

Dräger's range of medical accessories now provides new possibilities in the area of intensive care. For example, hospital staff can be relieved of routine activities when a signal indicates that a water trap must be replaced or a ventilator automatically adjusts settings of a connected accessory such as a ventilation hose. This enables the optimisation of clinical workflows.

### Communication within a range of centimetres

Integrated into a medical accessory by Dräger, a RFID radio chip transfers the information stored on the chip to a nearby reader in a medical device. Data is transferred over a short distance of only a few centimetres with a transmission power of 200 milliwatts. Software installed in the medical equipment processes the data and converts it into screen information, for example. This allows the device to offer new functions, such as the independent checking of hose connections or the automatic transfer of a patient's ventilation settings.

### Everyday use of RFID by ICUs

A daily scenario: A patient is prepared for transport from one Dräger venti-

lator or anaesthesia device to another. The RFID radio chip integrated into a RFID hose system saves the ventilation settings of the first medical device. Several background mechanisms take place once the hose is reconnected to a RFID-compatible device: The new medical device immediately imports the information relating to the accessory via a wireless connection. For example, the ventilator or anaesthesia device detects whether the hose is compatible with the device version and the set configuration. The correct connection of the accessory can be checked automatically as well. The new device then saves the information of the accessory without requiring any additional manual configuring. The physician or nurse simply confirms acceptance of the data. RFID is also suitable for other tasks: Wireless RFID technology makes it possible to save the date of the first usage on the accessory's radio chip, for example. Once a predefined period has expired, the device automatically reminds the user to replace the component.

**Tiny but powerful**  
RFID radio chips are ideal for integration into medical accessories and devices due to their small size. They feature outstanding functionalities for sending and saving data at the same time. This technology does not require a line of sight between sending and receiving module as required with barcode readers, for example.

Report: *Andreas Otto, Senior Product Manager, Dräger Medical AG & Co. KG, Germany*



Norbert Reekers

Peter Mildenerger

Jarmo Reponen

Peter Gocke

Armin Gärtner

Josef Brunnhuber

Dennis Feiler

Jörg Lemke

Stefan Walther

## PACS and more!

More interesting topics, more practical tips, more visitors

The second PACS and more! seminar took place during the DICOM 2010 meeting at Schloß Waldthausen in Mainz. Organized by EUROPEAN HOSPITAL and jointly facilitated by Dr. Norbert Reekers, General Manager Sectra Medical Systems GmbH Germany and Professor Peter Mildenerger, organizer of the DICOM meeting, the event more than matched its name.

**Regional and national PACS solutions – the Finnish situation in the healthcare ICT framework** was reported on by Jarmo Reponen, Research Manager at FinnTelemedicum and President of the Finnish Society of Telemedicine and eHealth at the University of Oulu, Finland. In Europe, Finland is a forerunner in digitisation and teleradiology: 21 of the country's hospital districts have worked with PACS since 2007, and about 81% use teleradiology.

The Finnish Government decided to set up a national e-archive in 2006; the first phase began at the beginning of the year. This network already provided the best possible prerequisite. However, Jarmo Reponen still saw problems with the national exchange of images: The strict guidelines on data protection currently require a patient's consent before data can be transmitted.

Peter Gocke, CIO at the University Hospital Eppendorf, discussed the return on investment (ROI) for IT products. It is not always easy to determine this – particularly in the case of complex IT processes, such as the introduction of an electronic patient file (EPR). Calculating digitization advantages – e.g. fast data availability, reduction of redundant entries – must be offset against the initial extra cost, which is difficult to assess. In these cases ROI calculations should not be viewed from a purely static viewpoint but have to be carried out at different points in time.

However, for the acquisition of individual IT components, such as for server

virtualisation, the costs are relatively easy to determine by comparison with the costs of maintaining the current status. The rule is that the determination of the ROI only makes sense when the acquisition can be amortised within its expected service life (for IT products about three years).

Josef Brunnhuber, head of IT at the District Hospital Altötting, Burghausen, reported on successful process optimisation due to IT systems used in the hospital's A&E department. The first step consisted of recording the EMR path, which starts and shows the processes of EMR screening, via diagnosis, to the final treatment report. In this, the complete integration of all IT solutions into the HIS as the control system proved very important. An electronic screening sheet formed the basis of any further proceedings, for example: What priority does the patient have? To which department should he be transferred? Does it have the capacity? Once answered, the patient may be transferred to the radiology department where the RIS and PACS utilise existing data from the HIS and, vice versa, the resulting images are then re-fed into the system. The introduction of a dictation workflow was important in this process: The spoken information was recorded using the conventional Dictaphone, but was then tagged as 'priority'. Language recognition then translates the dictation via the server and transmits it, as a priority, to a typist. Acoustic as well as an optical replay of the translated dictation, which can be corrected immediately, follows. The report is then returned to the originator, consultant or head of department, printed and handed to the patient.

The advantages of a good IT strategy also apply in smaller hospitals and surgeries. Dennis Feiler, Managing Director of DFC Systems GmbH, Munich/Mannheim, said that insufficient IT structures harbour the danger that legal requirements cannot

actually be met, to say nothing of the economic necessities, because an IT outage can bring a company to its knees. Thus he insisted that surgeries and smaller hospitals should think about installing sensible IT structures, even though the implementation may initially appear costly.

A number of functional, legal and technical prerequisites should be met to ensure that investments produce the biggest possible return. He also views server consolidation as the way forward for surgeries: The trend is moving away from singular systems towards a migration to unified servers with a maximum of two to three redundant systems.

Jörg Lemke, Business Development at NetApp, discussed the unified storage potential in 'cloud computing'. The consolidation of applications and servers into one system raises the questions of how this one system should be built and where located. One alternative to the established silo solution on site would be to outsource the required services. As with other outsourcing, the advantages lie in high flexibility and efficiency. The agreed services are only used as needed and billed on a pay-per-use model. Apart from the elimination of acquisition costs a cloud service brings further financial advantages – maintenance and security, for example. Additionally, the round-the-clock availability of the system without any downtimes, as well as upgrade options, are part of ROI calculations.

Whilst Stefan Walther, CIO at the University Hospital Düsseldorf, outlined some benefits of IT – workstation problems solved within an hour, portal systems adapted to processes in about 85% of cases, many different forms already fed into the system, IT teams that train staff to use the hardware and software – he said: 'New IT components could be possible that allow a configuration with less equipment. The use of new applications would also allow completely new ways of thinking and the use of IT could be increased significantly through a simplification of use that would increase user acceptance. Moreover, IT resources could also be increased considerably under adherence to strict guidelines as new systems allow unconditional configurability.'

*continued on page 11*

During the *Forum MedTech Pharma* (30 June to 1 July, Nuremberg, Germany – Texas Instruments discussed the impact of semiconductor innovation on the development of medical equipment. 'As an integrated circuit (IC) provider we sell both analogue and digital solutions to system houses, which then integrate the product,' explained **Dr Karthik Vasanth**, Medical Business Unit Product Line Manager at Texas Instruments, during an interview with Daniela Zimmermann (EH). 'Our customers put their intellectual property and their know-how into the product. Similarly, we sell semi-conductor devices for cell phone applications, but we don't sell the final product.'

'We don't influence the market directly. But we do work very closely with our customers, who do influence the market. They have very specific requirements, so that they can make products that change the medical market. A very good example would be a portable ultrasound system – typically in a hospital, you have very large ultrasound machines, but now companies can make portable systems because we provide them with semi-conductors that are very small and very efficient. To be able to do this we talk to our customers to understand their market and then we design our chips to help them to succeed in that market.'

It's the semi-conductors not the technology that are driving innovation in the market, added **Daniela Koeppe**, Medical Communications Manager at Texas Instruments. 'They enable devices to be connected, to be more portable and have lower power, and so on. So, we do influence the market through this. Our customers have the final product, but it's our technology that's driving innova-

tion. We need to understand the needs of the end users. A doctor who uses an ultrasound machine needs to understand the technology that's in the device. We try to educate the people who work in a hospital environment to make sure they have an easier time to adopt innovations. We don't go out to hospitals directly but we use public opportunities to talk about what semi-conductor innovation can do in this market.' Hence the forthcoming Texas Instruments talk in Nuremberg.

About three years ago, Dr Vasanth continued, the firm saw that electronic medical devices could become a very large market. 'So, we redefined how we can tie into the medical space.'

### Small portable medical devices

The portability of medical electronic devices is highly desirable and this requires lower power and smaller size. 'To enable these new form factors while maintaining excellent performance, semiconductor technology is required to integrate the same functions into fewer components, which not only reduces the system size, but also the power consumption,' Dr Vasanth explained. 'The miniaturisation required to make this possible is due to the availability of high performance analogue and digital integrated circuits that provide excellent performance with low power and smaller area footprints. Over the last five years integrated circuits in certain areas (this is not a global statement) have shrunk in size by more than a factor of four, consume half the power and have better performance when compared to older technologies.'

### Telehealth and home care

Another trend that semiconductor innovation accelerates is the ability to couple imaging modalities, such as ultrasound,

## Semiconductors

As their size and power reduces, their contribution to breakthrough medical electronic devices inevitably swells

Semiconductor technology plays an important role in improving aspects of healthcare by making medical electronic devices more flexible, affordable and accessible



Karthik Vasanth

with basic patient monitoring devices and telecom connectivity, thus enabling the development of telehealth applications. 'We are talking about the basic innovation in IC technology that enables these products to be made,' Dr Vasanth pointed out. 'What we are seeing are ultrasound, or ECG, or blood pressure machines that can all talk to let's say a hand-held unit, which can transmit the image to some satellite or processing unit of a big hospital in a metropolitan area. The cell phone can actually become a platform for communication devices. You just have to make sure that the medical devices have communication capabilities to communicate with the cell phone. So, home care is one of the markets we are looking at.'

'But we are also talking about how low power Bluetooth chips can communicate seamlessly with a cell phone, which then becomes the gateway to the world. We also talk about telehealth in an emerging economy, or patient monitoring in all the existing developed countries.'

### Enhancing a healthy lifestyle

In addition, TI is exploring how consumer health and wellness devices might be enhanced by semiconductor innovation, notably by power reduction and integration. Single, highly integrated semiconductor chips can already measure, compute, display and transmit vital signs.

'As we reduce the power consumption of these applications we can enable continuous monitoring rather than spot checks. This technology, along with trendy applications, allows for new and innovative methods in personal healthcare. People can carry a device to monitor their pulse rate, or a device on the body that tells you precisely how many calories you are burning and how your blood pressure varies in the course of the day,' Daniela Koeppe added. 'Such applications could be integrated into a mobile phone, or pedometer, or in any type of equipment customers manufacture. 'You can not only connect this to a cell phone but also to a PC via a USB port, and then you can monitor your daily progress and even compete virtually with other people around the world – let's say on your jogging trips or during cycling races.'

### Implantable monitors

Implantable devices have benefited hugely from miniaturisation, taking them far beyond their original role as aids to help cardiovascular patients. Daniela Koeppe referred to implantable devices to manage pain and others for nerve and deep brain stimulation. 'This is a little bit further out, but such miniaturisation is definitely coming.'

Naturally, in terms of medical implants, the smaller the device the better. 'Yes,

miniaturise – but also drive the power down, because these devices need to work for a long time on a battery with no replacement.'

So, another challenge for Texas Instruments, a name almost synonymous with miniaturisation, but the company still aims to go further, by surmounting size and power obstacles that stand in the way of electronic progress.

### Texas Instruments Inc.

Over 75 years ago, when Texas Instruments began as a company in the oil fields of Texas, no one could have foreseen the firm's immense impact on the way the world would run today.

52 years ago, engineer Jack Kilby joined the team and, in that same year, conceived and built the first electronic circuit in which all the components, both active and passive, were fabricated in a single piece of semiconductor material half the size of a paper clip. He received the Nobel Prize for Physics.

That early micro-chip made mass production possible and ultimately enabled the Internet, PCs, cell phones and so much of what we now take for granted.

TI's engineers, who also produced the first commercial silicon transistor and first electronic hand-held calculator, continue to lead the way in digital signal processing and analogue technologies – the semiconductor engines that drive our electronic age.

Along with R&D in a broad range of electronic areas, Texas Instruments components are instrumental in the development of medical devices that are changing the way healthcare is delivered.

Today, the integrated circuits global market is worth around US\$2.50-3.0 billion annually.

# Voilà! French e-health goes online in 2010

**France** - The hosting service has been selected, software standards have been published, and on 11 December 2010 any French citizen will be able to open a file and begin creating a secure, personal electronic health record (EHR).

If the agency charged with this ambitious programme meets the deadline, France will suddenly jump to the leading edge of e-health worldwide, rivalling advanced national programmes in Canada, Sweden and Denmark, as well as benchmark regional programmes implemented in Spain and Italy.

Launched with much fanfare in 2004, the *dossier médical personnalisé* (DMP) was promoted as the *pièce de résistance* for reforming France's healthcare system, expected to bring over €3.5 billion in cost savings annually for the state health insurance fund.

The July 2007 deadline set by the legislature passed, the programme became a national embarrassment and, in 2008, a joint commission of three government ministries declared the DMP officially dead.

Stubbornly, Health Minister **Roselynn Bachelot** re-launched the DMP in 2009. The solution may have failed, she said, but the need for patient-centred management and savings for the health insurance fund had not gone away.

Against all odds and in record time, the newly created agency charged with delivering the new DMP moved quickly and convincingly, securing the necessary funding, overcoming legal and technical problems and announcing the ambitious deadline.

During the national Health Information Technology exposition in Paris, *European Hospital* spoke with **Jean-Yves Robin**, the head of ASIP Santé (Agence des Systèmes d'Information Partagés de Santé) who is leading the French charge to the frontline of e-health in Europe.

He chafes at the suggestion that France is going to pull a rabbit out of its hat in December, suddenly to become the only country to offer a nationally coordinated healthcare record. 'This is not a magic trick. This is the fruit of years of work,' he said dur-

ing our *European Hospital* interview. 'We are not creating something completely new but re-launching the DMP, which is to say we are not re-inventing everything but instead pulling together several years of pilot programmes, development of security systems and tapping into independent efforts such as the medication records and the record of medical acts from the national health insurance agency.'

'At the moment, yes, France is behind other countries that have launched impressive regional programmes or have focused on specific functions, such as pharmacy or scheduling,' Jean-Yves Robin conceded. 'We have had problems with governance and leadership of projects, but those issues are now settled.' Legal disputes on patient identification and the rights of patients to direct medical records are resolved.

A key strategy, he explained, was to clearly separate the DMP into two different programmes, though both share the same designation in French as DMP.

The DM-Patient to be launched in December is an EHR aimed at helping citizens organise health records for consultation with their general practitioner (GP) and other healthcare providers, such as home care providers or emergency caregivers seeking medication histories and a summary of recent surgeries.

The DM-Patient, which will be developed progressively over the next few years, is an electronic patient's record (EPR) that will be shared among healthcare professionals, specialists and clinicians with detailed reports of a patient's care and will include exam results, e.g. lab reports and medical images.

In March, ASIP-Santé selected an industry consortium of French-based companies to host the DM-Patient made up of Santeos SA, an affiliate of Atos Worldline, and Extelia, an affiliate of La Poste, the national postal

## Starting in December, a personal health record will become available for every citizen



Jean-Yves Robin

service, as well as Softway Medical.

ASIP-Santé has also published specifications for software developers, called ASIP 1.0, for building components of the DM-Patient, and the agency established a framework for system interoperability that will have wide influence beyond the public records directing standards for the DM-Patient as well.

'In five years France will clearly be the EHR leader in Europe,' said Jean-Yves Robin. 'We have a great healthcare system delivering great medical care, and soon we will have the information infrastructure that assures this quality will be maintained along the entire patient pathway.'

Hospitals cannot care for patients beyond the walls of their facility, he explained, needing the cooperation and coordination of care with GPs and the support services of the community where the patient lives, whether it is with the pharmacy or a radiology clinic.

Bringing the hospital records and the information generated by these community services together in a single file becomes critical.

'For those who interact often with the medical system and really need a DM-Patient, there is a wealth of information they can place in the file,' he pointed out. 'Yet it is true that for the young, or those who rarely need medical services, it has a limited value and they likely will not be motivated to create a dossier.'

ASIP-Santé will create a network of health professionals to assist patient-citizens to set up their files and request required information, he said.

Rather than imposing a medical record from the top down, France has chosen a unique approach of creating consumer demand to motivate general physicians and privately run laboratories and radiology clinics to align with IT requirements for record-keeping.

'We are not putting a gun to their heads and saying, you must do this,' Jean-Yves Robin said, acknowledging that the intention is to create a demand on the part of patients who need the file to progressively influence doctors and clinics to provide information in the specified formats.

While he soft-pedals this approach – hoping to influence and persuade France's recalcitrant and defensive general practitioners to align with the programme goals – he also has been given an iron fist to place inside this velvet glove.

The newly enacted French hospital reform law gives him the power to freeze health insurance reimbursement for those who do not conform to the requirements.

Report: John Brosky



Now an 80% dose reduction can mean...

## EPRs dramatically speed up Chlamydia treatment cycle

**United Kingdom** – The introduction of electronic patient records (EPRs) can 'dramatically' speed up the Chlamydia treatment cycle, more than doubling the number of people treated within two weeks of a test result, according to research led by Dr Gary Brook at the Patrick Clements Clinic, Central Middlesex Hospital, London, and published in the journal *Sexually Transmitted Infections*.

The researchers base their findings on over 100 sexual health clinic patients either treated in the first three months of 2007, before EPRs were introduced, or during the first three months of 2009, after the shift from paper records.

The date of first attendance at the clinic, first positive test result, first attempted patient contact, and attendance for treatment were all recorded for each patient over the two separate time periods.

Between 2007 and 2009 the average time taken to treat a patient after a positive Chlamydia test fell by 11.5 days to 3.5 days. The average time between first clinic attendance and treatment fell by 9.5 days to 11.5 days – despite test results taking two days longer to arrive from the laboratory.

The proportion of patients treated within two weeks of receiving a positive test result soared from 38% in 2007 to 94% in 2009. Patients were contacted an average of seven days sooner in 2009.

EPRs also cut the recall time by eliminating time consuming administrative procedures, such as searching for notes, and boosting efficiency, because many of the paper records had not been updated and so contained inaccurate contact information.

This in turn allowed for significantly more patients to be recalled by telephone: 59% were

contacted in this way in 2007 compared with 88% in 2009.

Speedier contact ensured earlier treatment. 'The longer a [sexually transmitted infection] goes untreated, the more risk there is of onward transmission and of clinical complications,' the authors point out, adding, 'Appropriate use of technology greatly improves our ability to treat patients rapidly, and we should strive to use all available methods, for the good of our patients and the betterment of public health.'

Their conclusion: Clinics still running paper based records should strongly consider switching to EPRs.

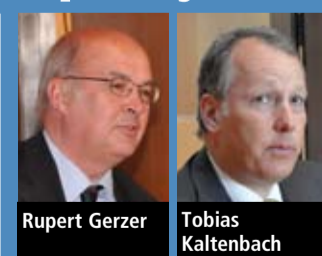
Source: *BMJ* specialist journal 'Sexually Transmitted Infections': The effect of electronic patient records [EPR] on the time taken to treat patients with genital Chlamydia infection *Sex Transm Infect* 2010; doi 10.1136/sti.2010.042432. [www.sti.bmj.com](http://www.sti.bmj.com)

## Aerospace medical expert joins future hospital programme

**Germany** - In April, the Asklepios Future Hospital (AFH) Programme, a multinational cooperation of 25 business partners, gained a new partner, Professor Rupert Gerzer, Director of the German Aerospace Centre, an expert in distance medical services.

In a partnership begun over five years ago with Microsoft and Intel, Asklepios designed the AHF to develop special hospital and entire healthcare system information technologies (IT). In 2006, the partners launched the *OneIT* project, which connected the Asklepios clinics with a uniform IT-system.

The next step will be to connect all players in the healthcare market with the patients via information technologies, Dr Tobias Kaltenbach, Chairman of Asklepios Hospital Group and head of business management explained.



Rupert Gerzer

Tobias Kaltenbach

Thus Prof. Gerzer entered the AFH programme. At the Institute of Aerospace Medicine the professor is primarily responsible for the health of European astronauts, and also research development. Further basic demands are to provide tailored services for the astronauts, a functioning system that provides them with information, particularly if far way – in outer space, for example – and finally, data privacy. 'All these tasks will also be general in future medicine,' Prof. Gerzer pointed out. First, prevention will be a vital component, to reduce overall costs in healthcare

systems, he said. Then, individual, automated systems for personal healthcare will not be avoided in future: A shortage of physicians makes the development of tailored medical services necessary.

Additionally, a big future challenge will be to offer patients the right treatment at the right time. 'A future task will be to retrieve essential information from the growing data graveyards in time, while ensuring data protection,' he pointed out.

Only good IT solutions can solve all these tasks. In this area, the Institute of Aerospace Medicine is in step. For a decade the institute has been an official partner of the German armed forces (Deutsche Bundeswehr), developing efficient, secure communication pathways in telemedicine. Hence the AHF partners were pleased to welcome aboard their new partner.

Report: Bettina Döbereiner

# Health informatics in practice

The *Health Informatics Congress\**, held in the UK this April, revealed how IT is helping health Trusts across the UK to take innovative steps in the way they respond to patients' needs

The Clinical Showcase session examined how Trusts are coping with new patient administration and reporting systems and, in particular, how *Cerner Millennium* and *Lorenzo* systems are being implemented. While advantages were clear, the session was also informed of the challenges overcome by Trusts to begin to reap the benefits of installing such systems, reports *Mark Nicholls*.

The session also highlighted how new technology has exposed issues of concern, particularly in laboratory result reporting.

It also looked at how a UK ambulance service is using new technology to record patient details at an emergency site and transmit these to A & E hospital staff ahead of arrival, thus enabling better treatment preparation.

In addition, representatives from the West Midlands Strategic Health Authority outlined areas of IT best practice across its whole region with its *IT Treasure Map*.

## Learning to love Cerner Millennium

**Dr Tony Berendt**, Executive Medical Director of the Nuffield Orthopaedic Centre in Oxford, outlined the ongoing challenges faced by his Hospital Trust in implementing the *Cerner Millennium* patient administration system (PAS), acknowledging the well-documented issues with the installation of *Cerner R0*, from as early as 2006, at the acute specialist NHS Trust, which offers specialist and routine musculoskeletal services and rehabilitation.

'Our PAS function was poorly developed and we had major disruption to our business processes and patient administration and, as a result, our performance rating with the HCC (Healthcare Commission) was poor,' he said. 'There were numerous subsequent "fixes". We also knew it was problematic in other sites but there had been successful implementations. We identified solutions; the need for strong clinical leadership, pathway redesign and better use of technology.'

Throughout, he said, the Trust remained convinced that EPRs are the way forward and a huge advantage over the usual transportation of paper records around hospitals.

Outlining other EPR advantages for clinicians, Dr Berendt pointed out that a review of notes that formerly took a month to carry out when compiled with paper records had been achieved within five hours electronically.

Nuffield Hospital made improvements, approaching an upgrade to *Millennium LC1* by rolling it out from one team to the next to reap the benefits of 'rolling enthusiasm' rather than a 'big bang' go-live approach. 'We decided to push ahead with the goal of making *Cerner Millennium* an integral part of our clinicians' lives,' he said, adding that while there are still issues, all clinicians are trained, notes are being signed off electronically and the Trust is already looking at future benefits with *Cerner*, including general practitioner (GP) communications, use of telephone messaging and patient lists and remote access to the system.



In an ambulance, a paramedic records data on the body mannequin graphic on Toughbook, for transmission to an A&E department

Future priorities include an enhanced *LC1* upgrade, new work flows, order communications and raised functionality.

His conclusion? It is possible to 'love *Cerner*' and *Nuffield's* implementation was progressing with the view that 'integrating EPRs is a key enabler of improvements in efficiency, safety and the patient experience'.

## CSC/iSoft Lorenzo

The session heard how a 'fictitious' NHS Trust has been established within the East Midlands Strategic Health Authority to demonstrate to clinicians the benefits of *CSC/iSoft Lorenzo*.

**Dr Tony Penney**, a Kettering-based GP who is also Clinical Director of Strategic IM&T for East Midlands SHA, said that not having a product deployed on site meant it could not be seen and felt, adding that, as clinicians, it is important to know what you are getting into. 'Also, if they can see the benefits of *Lorenzo*, they will start evangelising about it but, at the moment, until they are signed up for *Lorenzo* and it's almost deployed, they don't get a chance to look at it.'

The answer, he explained, is *CLINT* (Clinicians NHS Trust), an extra deployment of *Lorenzo* with 'dummy' patients on the latest deployed version. With 60 licences to operate this, there are various clinical scenarios within *CLINT* to offer clinicians an insight into *Lorenzo*. Each user is allocated a dedicated laptop, smart card and VPN token with support from the *CLINT* users group to discover more about *Lorenzo*.

'It is not a formal demonstration,' Dr Penney explained, 'but the aim is to familiarise clinicians with *Lorenzo* in small groups.' Rather than highlighting only design functionality enhancements, the aim is to give clinicians the 'feel' of *Lorenzo*.

Feedback is via a share-point site and within the *CLINT* group there users who know the product in depth and can offer support. The group also now has a place on the principal *Lorenzo* user group, where clinicians from 'live' trusts discuss usability issues enabling anything gleaned from *CLINT* users to be fed back to *CSC/iSoft*.

## Ambulances and IT

Ambulance Trusts are often the forgotten branch of the health service, suggested **Dr John Stephenson**, Medical Director of East Midlands Ambulance Service (EMAS) NHS Trust, who outlined how IT was helping the ambulance service to offer better care and potentially improve clinical outcomes for patients.

EMAS ambulance crews now use *Siren ePCR Suite*, an electronic patient care reporting (ePCR) system from *Medusa Medical Technologies*, which rapidly captures patient care data using touch-screen technology and provides comprehensive data analysis and reporting capabilities.

Connected remotely via GPRS, the system records the data on a *Panasonic Toughbook* and transmits it to the A&E department. 'These records are visible at the hospital

once they are recorded by the ambulance crew and are a good way of sharing information and decision making,' Dr Stephenson said.

Once a 999 call is received, it is fed to the crew's *Toughbook*. Once with the patient, pulse, blood pressure and other vital sign details are recorded, along with an ECG, there is a patient mannequin on the laptop to record injuries graphically, and a time-stamped interventions facility that records precisely when interventions took place to provide a highly-accurate record of patient care. All the data is transmitted to A&E staff for better briefing and preparation ahead of the patient's arrival. 'What they see from the ECG reading may influence the decision to take the patient direct to the cath lab rather than the emergency department,' he explained.

EMAS covers a population of 4.6 million people in a geographical area of 6,425 square miles and has 76 locations and 800 vehicles. With 1842 ambulance staff and 203 ambulance control staff, it handles 550,000 emergency calls annually.

While there have been transmission issues in rural areas and the problem of transmitting while a vehicle is travelling at speed, Dr Stephenson said solutions were in place to address this with 3G technology available.

An e-mail summary of what has occurred to the patient is also sent to the patient's GP with the information forming part of the patient's EPR.

Funding for *Siren* has been provided by the SHA, with training rolled out across the ambulance Trust and to hospital staff. 'This has been a major change for ambulance staff, from using tick boxes on paper to recording data on computer but for receiving locations they now have a real reference for patients, received in advance,' Dr Stephenson pointed out.

Future developments could mean spine connectivity, access to summary care records for ambulance crews to view a patient's allergies and current medication, working with the NHS Pathway triage system, and could see ambulance staff contributing to the patient's primary care record.

The system is established across Derbyshire and Nottinghamshire and will be rolled out across the whole of the EMAS area (six counties) by September 2011.

## Flaws in lab test results

With an EPR now potentially being built up from a number of sources, often with tests carried out at several different laboratories, a lack of uniformity in testing levels has emerged, which could mean confused and dangerous results.

**Dr Rick Jones**, Associate Clinical Director of the Yorks and Humber Programme for IT and Senior Lecturer at the Yorkshire Centre for Health Informatics, University of Leeds, presented the session *The hidden dangers of mixing clinical data across systems in the absence of scientific understanding*, to highlight this issue. 'Trusts are requesting analysis that is interpreted to see what is wrong with the patient. In the old world the hospital lab would work with the surrounding GP service.' But now, in a world, where IT has eroded boundaries, these tests can be conducted

at different laboratories, with many having slightly different interpretation levels and different reference ranges for specific tests. 'People are having tests done all the time at different laboratories in different places, but with this different data getting merged together,' he pointed out. 'If it is not consistent, we are getting inconsistent results.'

With the EPR, people are getting data from all over the country, but what is measured in Scotland, for example, may differ to what is measured in parts of England.'

Dr Jones pointed out that PSA testing for prostate cancer, where slightly different scales and interpretations for high or low levels can be used from one laboratory to another, could give results varying by as much as 20%, or variations in the classification of patients with chronic kidney disease and their eGFR (estimated Glomerular Filtration Rate).

He also underlined the need to align pathology standards and information standards in the UK. Over the last three years, work has been underway to address this issue.

## Harmonising pathology

**Dr Jonathan Berg**, Pathology Director for Sandwell and West Birmingham Hospital NHS Trust, explained that his team had taken steps to harmonise pathology testing with the Pathology Harmony initiative. 'When we looked at laboratories, we found that reference ranges were different from those in neighbouring laboratories for the same tests. Different labs had different criteria for abnormal test results.'

Early in the project, begun in 2007, the team saw the need to harmonise test results across all laboratories. It suggested 35 key areas of harmonisation of results and the need to work towards national consolidation of results and countrywide implementation. A national UK steering group on the subject has now been established.

## IT gems

**Dr Masood Nazir** and Nurse **Karen King**, from West Midlands SHA, used an illustrated *IT treasure map* of their area to highlight 'gems' that had set high standards and enabled them to meet their vision of introducing new IT systems to 'help to deliver better, safer and more connected care' and how 'better information was leading to better healthcare for every patient'.

Criteria for 'gems' selection were their easy, quick implementation, cost effectiveness and benefits. Examples included mobile working with real-time access to patient records at the point of care, Choose and Book in the Sandwell PCT area with a 90% referral target; successful implementation of *Lorenzo Podiatry*; better links between ambulance crews and A&E departments; an effective Electronic Discharge Summary system within NHS Hereford, and extending Choose and Book to book a physiotherapy appointment at University Hospitals Birmingham and NHS Hereford.

The developments are under the West Midlands Quality, Innovation, Productivity and Prevention Challenge.

'To improve patient care,' Dr Nazir explained, 'we need to share information and the spread of innovation will improve quality. Technology can also help improve patient safety.' The examples, he added, can be shared across West Midlands to reduce inequalities in healthcare.

Mrs King said future developments include wider sharing of PACS images and the use of telehealth.

Report: *Mark Nicholls*  
\* Organised by BCS  
(Chartered Institute for IT)



## Acuson SC2000 powered by a long-life workstation

The new *Dell Precision T5500 Long-Life workstation* has been adopted by Siemens Healthcare Sector to power its *Acuson SC2000* volume imaging ultrasound system.

The selected workstation is part of a larger programme by Dell's OEM division designed to provide longer manufacturing lifecycles, service and dependable system stability to address specific needs of the embedded and OEM markets. Available worldwide from Dell OEM Solutions, the workstation and newly launched *Dell OptiPlex XE*, are the firm's first offerings of several future long-lifecycle OEM-class platforms.

Siemens can now purchase the same platform for three years from its initial launch date with lower risk and costs associated with recertifying, revalidating or updating the service strategy with component transitions, software updates and BIOS changes.

### Dell points out the benefits:

- The OEM Long-Life programme offers extended product lifecycles and depend-

able system stability on established Dell products. Dell OEM handpicks specific component options to help ensure a committed long-life span so OEMs can plan engineering resources accordingly.

- Long-life products selected from this programme will continue to offer configuration flexibility and allow customers to take advantage of Dell's state-of-the-art build-to-order process.

- Specifically, the *Dell Precision T5500 Long-Life workstation* has two processor options from the Intel embedded roadmap, a list of stable components, specific supplier agreements on key components negotiated to support longer life product, and increased hub stocking levels to avoid supply disruption on single source parts.

- OEM customers have the choice of a dual-socket or quad-core workstation performance for space-constrained environments in a mini-tower form factor.

- The *Dell Precision T5500 Long-Lifecycle workstation* was collaboratively developed with customers like Siemens, which needed a durable, quality solution.



John Stephenson



Masood Nazir



Karen King

# Cloud computing

## Paris hospital group gained a virtual PACS that can handle 150,000 examinations – every month

L'Assistance Publique – Hôpitaux de Paris (AP-HP), the main public hospital system in Paris, France, is one of the largest of its kind in Europe. In 2005, the group voted to implement a PACS in association with Carestream Health to connect its 47 hospitals and centralise their data. This meant creating a network to cover 36 CT scanners, 31 MRIs, seven PET-CTs and 37 SPECT systems, which were linked to 37 RIS and 30,000 computers – of course from various vendors. During an interview with EH editor *Meike Lerner*, radiologist **Dr Daniel Reizine**, the project's coordinator at AP-HP, described the challenges and way in which the group coped with this formidably large project

The first challenge we faced was to vote for an enterprise PACS at all. First, plans were made in 2000, when we recognised that with the expected data explosion associated with multi-slice CTs and digital projection radiography, as well as the increasing pressures to improve operational efficiency, it would be impossible to continue working with film, Dr Reizine explained. However, at that time, enterprise PACS technology was not really available and PACS was quite expensive. So it took us another five years to make a final decision and create a plan of how to proceed.

The PACS server at each of these sites strips out the metadata of the acquired data set and sends it to the SuperPACS server at the data centre. This enables the data centre to serve as a registry by building a database of all AP-HP radiological imaging studies without creating additional copies of the image data. Having such a database enables the data centre to create global work lists for radiologists throughout AP-HP that can be filtered by any criteria (e.g. sub-specialty, stats, location of imaging, patient name, etc.). The PACS servers at each site constantly synchronise the data centre with every operation made

with the metadata, thus keeping it up to date. The SuperPACS server at the data centre is aware of the network topology. Thus, for example, if a physician in hospital 2 is requesting images created in hospital 1, he will select the study from a list provided by the data centre but the transfer of the images will go directly from hospital 1 to 2.

If the network between any site and the data centre is down, the site can still work independently with its local studies and synchronise the data centre when the network is up again. If the PACS server at one of the 20 sites is down, the other 19 sites stay fully operational. All servers in the SuperPACS solution run the same software and the operation and workflow of the overall system is achieved by properly configuring the relevant servers. This allows AP-HP to have virtually unlimited flexibility in deploying, expanding and further developing its enterprise PACS; and indeed, we implemented our enterprise PACS step by step over a period of 15 months, starting with the individual sites and completing with the data centre.

Looking to the near future we plan to embark on developments that will further improve our overall operational efficiencies. For example, we might reduce our number of clustered sites from 20 to only five or six, and put the data into one storage bay for each of the new clusters. Further, we may consider not only sharing data across our multiple sites, but *sharing workflow*. This means getting users in different locations participating in a single, common workflow across multiple systems and sites. That's the key driver of efficiency, and one of the biggest challenges facing healthcare information systems today.

Another aim, which I personally pursue, is to take advantage of a feature provided by the Carestream SuperPACS, which is the ability to use one desktop at the various sites to complete all radiology work (instead of using different systems with different performances – which is the case at the moment). Working only with the Carestream workstations would make an integration of additional features, such as speech recognition, much easier.

To conclude, our experiences with the SuperPACS and the way we chose to implement it in our organization were very positive and successful, and the process of optimising it is still going on.

### The Carestream SuperPACS

The SuperPACS architecture is designed to integrate multi-vendor, multi-site PACS into an enterprise solution. It uses existing PACS resources to share patient images and information while also delivering a global work list that balances examination reading among on- and off-site radiologists.

## More clouds on the horizon

### In the over-crowded IT landscape, the value and implications of cloud computing services are increasingly discussed

Given the task of archiving today's huge data files, not to mention additional services demanded of hospital IT staff, cloud computing could reduce many headaches. Via a healthcare IT supplier that offers cloud computing, a hospital would be able to use, over the Web, *virtual* hardware that provides higher levels of storage capacity and computing resources. In addition, almost any kind of healthcare IT application could be provided, e.g. for electronic patients' records (EPRs), computerised physician order entry (CPOE), e-prescribing and financial and administrative systems.

'In a scenario where healthcare providers are looking at automating processes at lower cost with higher gains, cloud computing can provide an ideal platform in the healthcare IT space,' concludes Sujith Eramangalath, industry analyst of Medical Imaging, Healthcare IT and Life Sciences IT at Frost and Sullivan. Additionally, the healthcare IT supplier can centre the infrastructure anywhere in the world, e.g. India, Africa, Brazil and China, where overheads are lower, which potentially could lead to cost reductions.

#### Accessibility issues

Currently, healthcare IT suppliers provide applications over the Web as a service through a subscription model (Software-as-a-Service - SaaS) to hospitals and primary care centre. With cloud computing, the suppliers could also provide infrastructure and applications as a service on a pay-per-use model, with hospitals using 'rented servers' rather than hardware owned and managed by themselves. 'Cloud computing could be seen as a boon to healthcare IT services as a number of hospitals could share infrastructure with a vast number of systems linked together - reducing operational costs but increasing efficiency,' the analyst pointed out. It would provide real-time availability of patient data for doctors, nurses and other support services within and well beyond the hospital, because medical professionals can access an EPR from any Internet-enabled device without installing any software.

#### Security: Private or hybrid clouds?

Given the importance of patient data privacy and security – everywhere – Sujith Eramangalath advised private clouds for hospitals because they provide 'greater control on the overall information processing systems and processes. However, he pointed out: 'private clouds can be expensive for small and medium-sized hospitals as the cost involved in setting up and maintenance is much higher. Private clouds are most suited for large hospitals and large hospital groups, which would gain from the flexible computing environment, quality of service and advanced security.'

A combination of in-house and external IT resources – a hybrid cloud – would be preferred among healthcare organisations. 'Since the hybrid cloud is a mix of private and public clouds, it would allow IT managers to switch applications back and forth between the clouds,' he suggested. 'Hybrid cloud would provide a high level of interoperability and meet the dynamic data requirements of hospitals. One of the most significant benefits of cloud computing is that it provides a scalable architecture for the hospitals to continuously add applications which may run on the cloud architecture.'

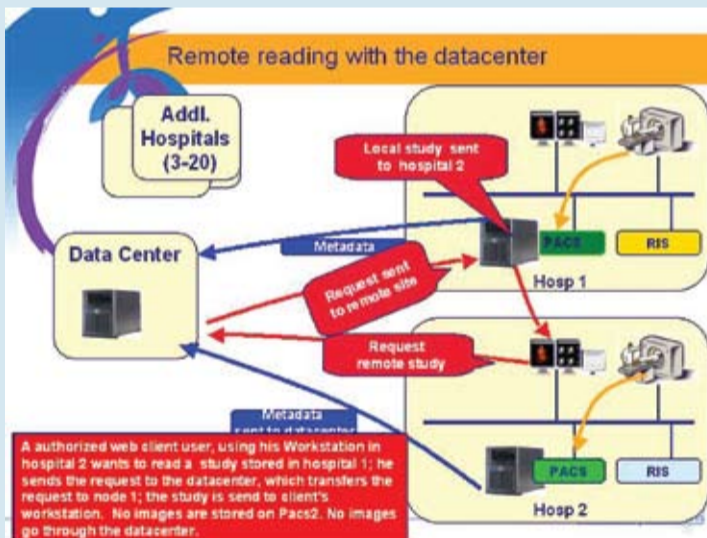
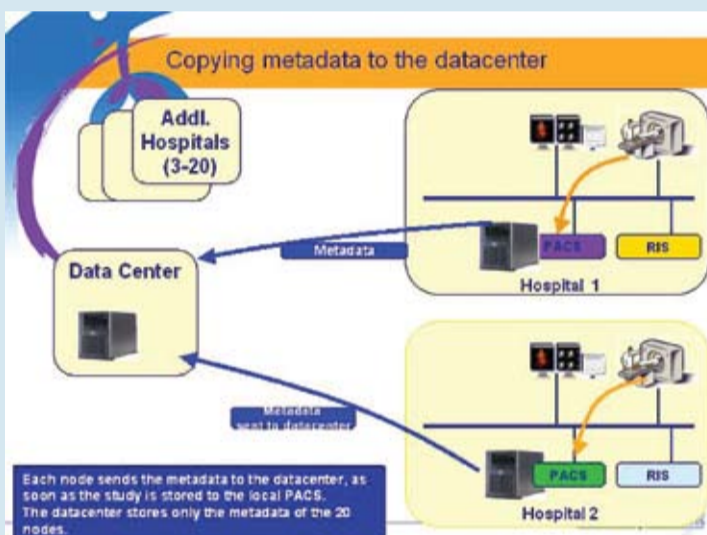
A key benefit of cloud computing is that costs are dependent on usage of the IT resources with the service provider illustrating a detailed cost breakdown that would help hospitals control costs.

But there are areas of concern such as issues of jurisdiction, security and access to patient data, particularly if the cloud computing suppliers to European hospitals had servers located in different parts of the world. 'There could be issues in applying European data protection laws in the location of the server,' the analyst explained. 'Currently, there

are no clearly defined views or laws for sharing patient data across the clouds and access of patient data in cloud architecture,' he said. 'IT vendors, who provide cloud computing services, must ensure maximum security to the sensitive patient data.'

However, Sujith Eramangalath believes the adoption of cloud computing would help standardise the infrastructure for healthcare IT solutions, in the current highly disparate situation.

Report: Mark Nicholls



After analysing our needs, we divided the 47 hospitals into three groups: two hospitals that already had a local PACS, 20 hospitals with at least one CT or MR scanner and 25 hospitals without CT or MR. We selected the 20 sites with at least one CT or MR for the new PACS installation, with the remaining 25 sites connected to them as appropriate. First, the networks of the radiology departments of each of the 20 sites were upgraded to a bandwidth of at least 100 Mb/s. Then, a PACS server with on-line fast storage was installed in each of the 20 sites and interfaced to the RIS, HIS and EMR.

The same configuration (hardware and software) was installed in each of the 20 sites. We increased the local storage progressively allowing an online storage capacity for at least five years in 2010. Each of the 25 hospitals without CT or MR ('Satellite Sites', mainly convalescent and long-term patients hospitals) was connected to one of the 20 sites for data storage. Reading and processing of data at the Satellite Sites is possible locally as well as remotely from its PACS sites.

The cloud architecture of the French solution employs the SuperPACS solution by Carestream Health, who was the provider and integrator of the enterprise PACS. A data centre with a SuperPACS server was established and connected to the 20 sites via a high-speed network. Every imaging study data set, acquired at each of the 20 sites or their associated satellites, is stored locally at one of the 20 sites.

...a cleaner image with the patient in mind.



## Olomouc aims for national telemedicine centre

**Czech Republic** – The teaching hospital in Olomouc aims to become a national centre for telemedicine. A telemedicine system is currently used by the hospital's Internal Medicine Department 1 for cardiac patients and almost a hundred patients are remotely monitored via a telesystem implemented by the hospital.

Further, in May 2010, this was the very first Czech medical facility to introduce a new fully automated CareLink system ([www.medtronic.com/carelink](http://www.medtronic.com/carelink)) a remote monitoring service connecting cardiac device patients to their clinic from home or away, enabling physicians to monitor remotely the clinical status of the patients with implanted pacemaker or implantable cardioverter-defibrillator (ICD).

'Building up the national telemedicine centre will need to be realised in several consecutive steps,' said department head Dr Miloš Táborský. 'The fundamental prerequisite for the creation of the whole project is to secure hardware that is efficient enough to be able to handle massive data in-flow. Fortunately, teaching hospital submitted the project documents to the Ministry of Education jointly with the Palackého University in Olomouc, and the chances of realisation are promisingly high because subsidies from the European Union

structural funds are also available for financing,' he explained. The national centre for telemedicine should serve the needs of patients around the Olomouc region and will also coordinate activities, such as telemedicine centres in other university and regional hospitals. 'We expect that we would have finally created the conditions for remote monitoring of over ten thousand patients. Presently we are at the clinic approaching the first hundred results and these are truly excellent. We can quickly respond to any negative changes in patients with implanted devices, thus preventing serious complications highly likely to occur without remote monitoring and quick intervention.

The remote monitoring of patients with arrhythmias is not yet funded through health insurance, he pointed out. 'The operation is only possible thanks to grants and cooperation with the pacemakers and/or ICDs manufacturers that provide patients with home monitors free of charge. Unfortunately, as yet re-imburement regulations for the medical work needed to evaluate data recorded from home monitors have not been systematically resolved. The provision of such a service is only possible due to the enthusiasm of the medical personnel involved. However, financing negotiations are already underway with insurance

companies. I suppose consensual proceedings of the code for the remote monitoring of patients will be successfully completed within the next year,' Dr Táborský predicted.

This project's big asset and advantage over other similar ones is that the centre-to-be is calculating with additional usage from the very beginning. There are already several suggestions on the table: Cooperation with the diabetology department on blood glucose home monitoring or cooperation with the pain department on full monitoring of their patients, especially for that suffering break-through cancer pain. 'It seems the general consensus about future healthcare system needs does exist, not only between healthcare providers and payers but also amongst political representatives. It is widely recognised that only full computerisation of the healthcare sector, and the introduction of e-Health systems, are the way to enable the future sustainability of the current system. Similar efforts leading to the creation of home monitoring centres are also progressing in other EU countries, with just about the furthest advance in Germany, where the payment code for remote patient monitoring for various disease conditions has been available since last year,' Dr Táborský pointed out.

So, hopefully, the future is about changes in Czech Republic too.

Report: Rostislav Kuklik

## The pros and cons of hospital IT

**Germany** - A study\* to assess the usability of hospital IT in Germany by focusing on effectiveness (functionality), efficiency (software ergonomics) and application support has been published by the German association of manufacturers of healthcare IT solutions (Verband der Hersteller von IT-Lösungen im Gesundheitswesen – VHITG). 4521 participants from 378 hospitals returned the online questionnaire, and 1003 of the questionnaires, from 158 hospitals, were completely filled in. They thus constitute the largest data pool on usability of hospital IT to date in this country.

### Time lost for patient care

The participants' assessment of the direct benefits of hospital IT for patient care was ambivalent: While on the one hand the availability of patient data and, to some extent, increased patient safety, the use of hospital IT on the other hand requires time, which becomes no longer available for actual patient care.

### User style guides needed

Many users pointed at an important problem of hospital IT: the different approaches to operating the equipment. The

introduction of stricter style guides for user interfaces might help alleviate this weakness. Platform-specific style guides, such as that of Microsoft Windows, could help users to master the equipment faster and more easily and they could potentially lead to a uniform interface across systems. However, such harmonisation is not solely the manufacturers' responsibility. It is recommended that the hospitals themselves use project-specific style guides when defining their parameters and develop an equipment operating concept to ensure unified software usage throughout their facilities. In general, application support was rated to be good, although user groups who deal directly with patients considered response times not always adequate.

### Role models

As for the availability of required information, intensive care and patient data management systems may serve as role models. In particular, intensive care systems successfully focus on the core objective of presenting data in such a way that they really support decision making. However, many other hospital IT systems scatter information in too many windows – which seems particularly

noticeable in radiology systems and which indicates significant differences in quality, be it in the products themselves or in their implementation in the individual hospitals.

Functionality of the sub-systems appears to depend largely on their integration into the overall hospital IT environment. In this, systems in radiology, intensive care and business management did well. Clinical workstations and patient management systems play a special role because they are the leading systems into which the other systems have to be integrated.

### Software ergonomics

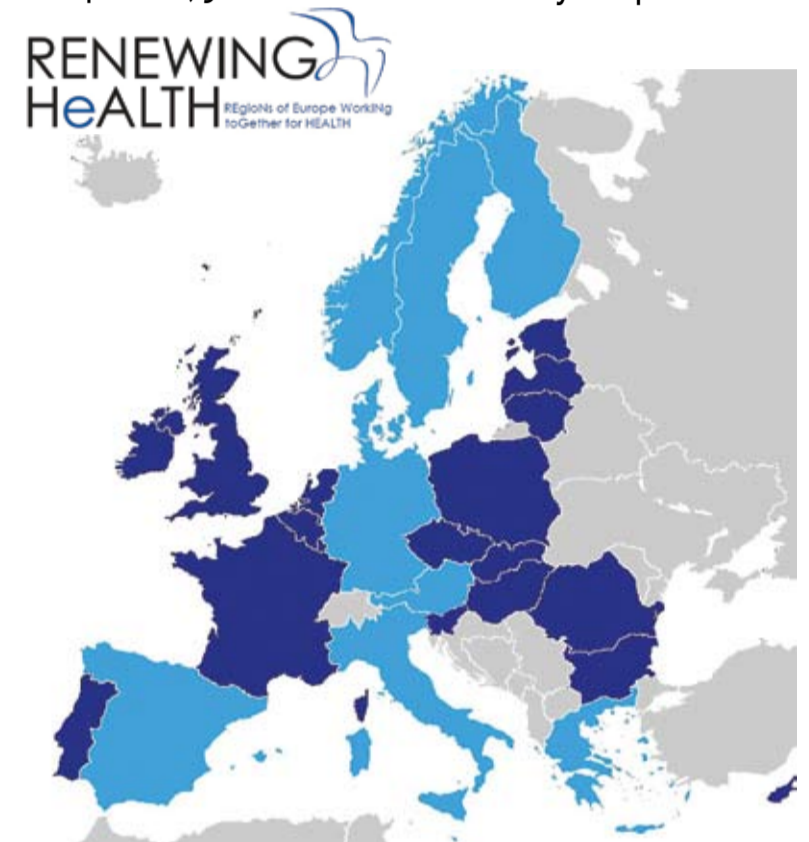
Specialised and department systems received overall better grades than clinical workstation systems in their more comprehensive approach. This supports the assumption that the better described the tasks and solutions a system is expected to support the easier it is for the software to comply with those expectations. The parameters to evaluate software ergonomics are: suitability for the task, ease of use and conformity to expectations. In general, all systems surveyed rated much better with regard to these parameters than SAP/R3, a widely used reference system.

\* The study (in German) is available at [www.vhitg.de/Ergebnisse/Publikationen](http://www.vhitg.de/Ergebnisse/Publikationen). Authors: BB Bundschuh, R Majeed, T Bürkle, K Kuhn, U Sax, C Seggewies, C Vosseler, R Röhrig (director)

## The Renewing Health European project

*Renewing Health* is the Veneto Region's response to the third *Call of Proposals* by the European Information Communication Technology Policy Support Programme (ICT-PSP). The project, which falls under the ICT-PSP financing plans, aims to facilitate the use of ICT-based solutions and services for citizens, the government, and businesses, as well as aiding their diffusion throughout Europe.

Begun in February 2010, the 32-month project has a total budget of €14 million, 50% of which is co-funded by European Union.



The Veneto Region is coordinator of the nine European Regions involved in the *Renewing Health* project. Along with Regione Veneto, these include the Syddanmark Region (Denmark), Northern Norway Regional Health Authority (Norway), South Karelia Social and Healthcare District (Finland), Norrbotten County Council (Sweden), Catalunya (Spain), Central Region (Greece), Carinthia (Austria) and the State of Berlin (Germany).

Its goal is to evaluate, through a systematic and common method, the use of the Personal Health System (PHS) and telemedical services that monitor patients with cardiovascular disease (CVD), chronic obstructive pulmonary disease (COPD) and diabetes. The term PHS means both the wearable/portable devices used to monitor some clinical parameters and the integrated telemedicine services for the remote data control. The study, based on large scale pilot trials, aims to provide objective results on the effectiveness of the assessed services and promote their broader diffusion.

MAST (Model for Assessment of Telemedicine), the methodology used for evaluation, is based on Health Technology Assessment principles; its general structure follows the Core Model of the EUnetHTA project.

The telemonitoring services included in the project, already existing or in a pilot phase, have been designed to give patients a central role in the management of their own diseases, fine-tuning the choice and dosage of medications, and help to detect early signs of worsening in the monitored pathologies. The analysis of these services will be based on two different organisational models: in the

first, the patients themselves will use the devices for data collection, while in the second, the home caregivers will carry out the measurements.

The expected results are of an *economic nature*, because the project will allow a containment of the healthcare expenditure while improving the quality of service to the patient; of *technological nature*, through the large-scale validation of telemedicine systems; but mainly of *clinical nature*, thanks to the assessment of the system's clinical efficiency. In order to guarantee the validity of the results, some important 'actors' are involved:

- **E-health competence centres** for each country: Arsenal.IT – Veneto's Research Centre for e-Health Innovation (Veneto Region), Medcom International (Syddanmark), Lulea Tekniska Universitet (County of Norrbotten), Norwegian Centre for Integrated Care and Telemedicine (Norway), Catalan Agency for Health Technology Assessment and Research (Spain), VTT Technical Research Centre (Finland), e-Trikala SA – Telecare Centre of the Municipality of Trikala (Greece), TSB Innovationsagentur Berlin GmbH (Germany), KABEG (Austria).

- **The User Advisory Board**, the committee representing the different categories of users of the services foreseen in the context of *Renewing Health*: patient and healthcare professionals.

- **The Industrial Advisory Board**, consisting of a team of experts in several fields, e.g. management of clinical data, standards, open sources, business trends in the personal health system sector and semantic integration.

# MIT Medical technology and IT *must* be combined



Armin Gärtner

Here's a scenario: A bug has entered the system. Nobody knows how and what it is. What is clear is that, due to the problem with the imaging plate readout, the X-ray examination just carried out must be repeated.

Who, in the hospital, is ultimately responsible for this situation?

The IT department is likely to point the finger at radiology or the purchasing department, claiming the even is an equipment problem. They, however, are likely to knock the ball back into the IT department's court – the bug is, after all, affecting the IT network. Finally, the third party is the X-ray equipment manufacturer, suspected of introducing the bug during the last systems upgrade.

Everyone agrees: This is no way to constructively deal with the problem. Up to March this year there had been no guidelines, as such, on how to deal with these – quite recent – types of problem. 'However, since the introduction of the ICE 80001 the rule has been that the legal requirements for medical products also apply to medical products to be integrated into an IT network "with a view to reliable operation within the network",' says IT specialist Armin Gärtner. 'IT networks that integrate medical products therefore turn into medical networks – but the network itself is not a medical product.'

The norm does not offer any strict specifications; instead it provides suggestions for a risk management approach to ensure the integration of different types of equipment from various manufacturers into the IT network. 'The user is in charge here,' Armin Gärtner emphasised in his lecture during a recent *PACS and more!* seminar\*. 'The manufacturer is not responsible for the safety of the integration into an existing IT network. Although he has to provide all the necessary information, the actual implementation remains the responsibility of the end user. This is why the IT department should already be involved at the point of purchase. When, for instance, an MRI scanner is purchased, an additional 20% of the acquisition cost is required for the network integration.' At the very latest, these costs become clear when we look at the potential risks of systems integration inherent in the installation itself, the remote service or the technician's notebook.

Accordingly, this realisation has far-reaching consequences, as the current structures and the division between medicine technology and IT has to be abolished. 'A modern process assessment confirms the need to break down the old patterns and combine the two disciplines in a new department – experts talk about MIT, i.e. Medical IT,' he explained. What exactly this new type of department looks like and what role the manufacturer plays depends strongly on the respective objective of a hospital. The ICE 80001 does not deliver any authoritative answers, but as a process norm provides the incentive for a lively discussion on the philosophy of acquisition and maintenance of equipment.

'The ICE 80001 presents, at the centre of things, the question How much safety can a hospital afford?' he pointed out. The above-mentioned process optimisation and enhanced networking of IT and medical technology obviously come at a price. 'On the other hand,' he added, 'the hospital operators need to compare these costs to the

breakdown and down-time costs per day of, for instance, a CT scanner, to say nothing of the additional effects on the patients.'

The question of what impact these changes will actually have on the manufacturers of medical devices remains. 'Within the context of conformity assessments, the manufacturers obviously have to

think about how they can equip their products for long-term use within a changing network. This includes, for instance, considerations as to the operating system used. The best solution can only be achieved through a dialogue with the end user,' Armin Gärtner concluded.

The ICE 80001 plots the course towards safe and stable networks,

but it is up to hospitals to decide on the actual implementation.

Report: Meike Lerner

\* Appointed official telemedicine representative at Sana MTSZ Stuttgart, during this year's PACS and more! seminar, held during the DICOM meeting in June, at Schloss Waldthausen, Mainz, Germany.

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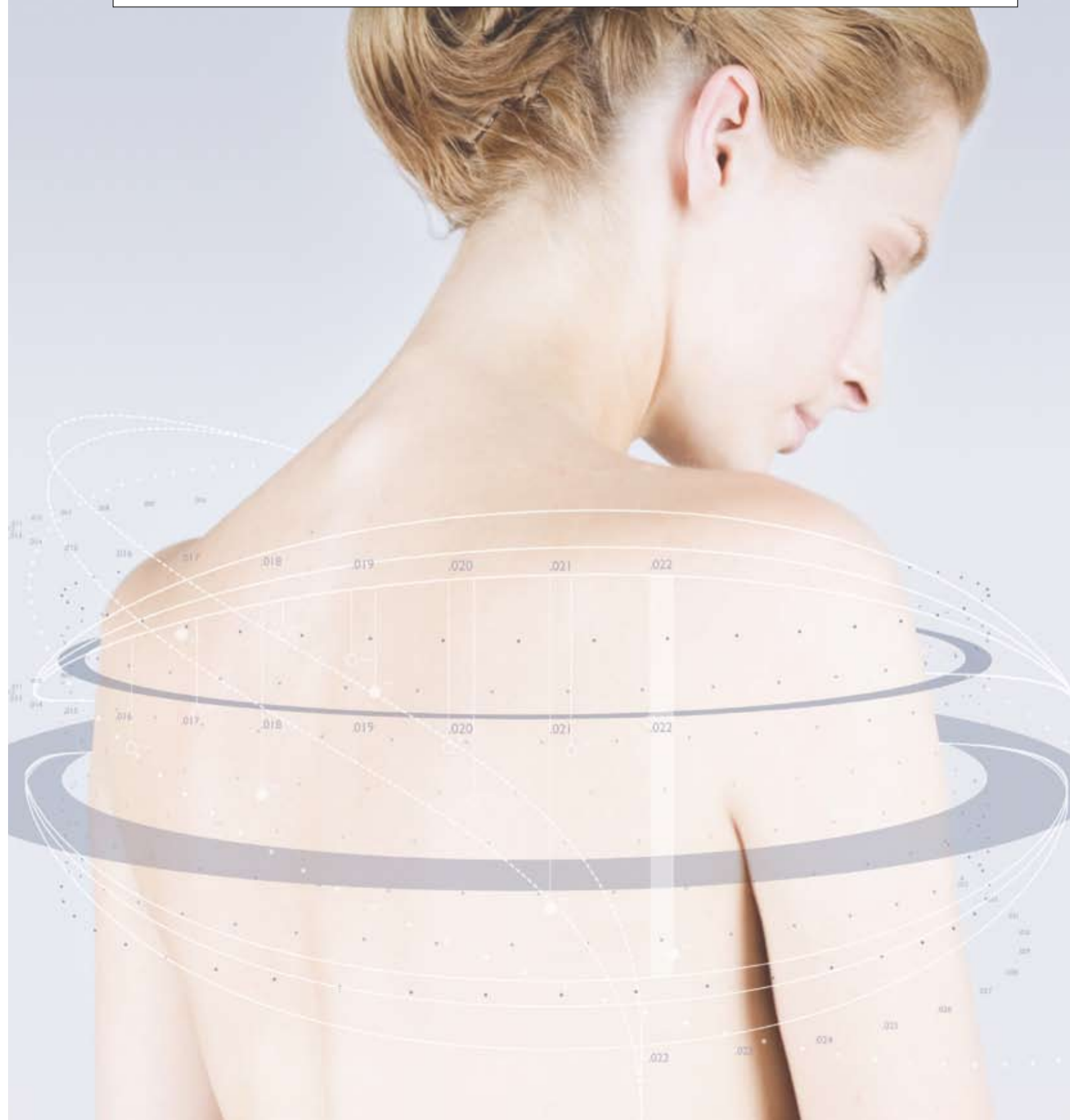
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# CT and US co-registration



Alice Gillams

## RVS raises radiofrequency ablation success

Dr Alice Gillams, who heads the image guided tumour ablation programme at University College London Hospitals (UCLH), reported at this year's ECR that Hitachi's Real-time Virtual Sonography (HI RVS) fusion imaging technique can achieve more precise radiofrequency ablation (RFA).

During the procedure a real-time ultrasound image is displayed simultaneously with a corresponding CT virtual multi-planar view, reconstructed from a stored volume data set. Thus the two imaging modalities provide a direct comparison of lesion location and more precise monitoring of interventional

the need for repetitive interval scans. So there are clear advantages regarding time and radiation dose.'

Of course there are tumours that cannot be shown with ultrasound, for example those in the hidden liver area, where the lungs descend in the costophrenic recess. The same is true for large patients or those with a fatty liver where the portion of the superficially visible liver attenuates the ultrasound beam. 'Looking back at an ablation experience of more than 15 years we definitely can say that since we opted for the real-time co-registration package and the software, we could perform much more precise treatments in a lot of patients – so the patient benefit increased significantly. That has been recognised by a lot of hospitals starting ablation programmes and many of them are ready for this specific expenditure. So the method surely will be more widespread in the near future.'

The technology is mostly co-registered with CT, however, Dr Gillams added: 'Every now and again, we co-register with MRI data sets.'

US and CT co-registration of a sub-cm melanoma liver metastasis, which was successfully targeted and ablated



procedures – without additional radiation exposure. The system is also time and cost effective.

RFAs have been performed at UCLH since 1994; the special co-registration software was installed in 2005. Thus, considerable experience has been gained over the past five years in the use of RVS, allowing progress in ablation for many different types of tumour in different organs, such as the liver and kidney, and occasionally, Dr Gillams pointed out during our EH interview, other 'unusual' sites.

The success of RFA strongly depends on the precise localisation and diagnosis of the extent of a tumour. In addition to the fact that the location of a tumour in a CT imaging slice varies according to patient position and respiration, the optimal depiction of several liver tumours depends on imaging at a specific point in the contrast enhancement cycle, which is often transient. Dr Gillams work has focused on minimising the problem by co-registration of the CT data set with real time virtual sonography.

'Real-time targeting is essential because liver motion is not just translational but often rotational,' Dr Gillams explained. 'Knowledge of the exact location of a small tumour on CT often allows us to appreciate subtle alterations in echogenicity on the ultrasound image, which can then be targeted. Once the two data sets are co-registered, the tumour can be located on the CT image and then targeted in real-time with ultrasound.'

Working with co-registration has shown positive results. 'The way co-registering makes a difference is that we can perform the procedure much more precisely and much quicker, with-



US-CT co-registered image during the ablation of a breast cancer metastasis located adjacent to the hepatic vein. At this stage an echogenic area is starting to develop around the active portion of the electrode

### Co-registration advantages

'Very often, you cannot see the tumours so well with just the ultrasound, or you may be able to see them but only transiently. So, if you can co-register them with another imaging modality, where you can see the tumours very well, then you can have the best depiction of where the tumour is and then, equally, the real-time feedback on your needle being inserted and positioned correctly within the tumour. So you have the best of both worlds.'

Asked why UCLH chose to use the Hitachi's RVS, Dr Gillams pointed out that not many manufacturers produce the real-time co-registration package and special software. 'You have some hardware, which is the electromagnetic sensor, but most of the development is the software. It's something additional that you buy when you buy the Hitachi machine. I also find that the Hitachi has very nice interventional ultrasound probes, which allow easy intercostal access and you can even insert your needle through the middle of one of their interventional probes.'

# The 26th Iranian Congress of Radiology (ICR2010)

Tehran, Iran – More than 2,500 radiologists, radiology residents, radiology technologists and physicians with other specialties attended Iran's most prestigious professional radiology meeting in May

Convened by The Iranian Society of Radiology, the ICR2010 Congress was planned around four main themes: urogenital, cardiovascular, molecular imaging and radiology education & research. Along with these, various themes in all medical imaging fields were presented in scientific lectures, interactive workshops and round tables by 25 lecturers from various areas of the world, including Europe, America, Asia and Australia.



Prof. Maximilian Reiser, University Clinic Munich, Germany



ICR President Mahyar Ghafoori MD



ICR Executive Committee Member Abdorrasool Sedaghat MD

Sounds from a traditional Iranian orchestra welcomed participants at the opening of this year's congress



The GE Healthcare booth

More than 170 scientific abstracts were submitted via the congress website. After the review process, carried out by 35 reviewers in 13 fields, 155 abstracts were accepted. Among these, 100 abstracts were accepted as oral presentations and 55 as electronic poster presentations. Finally, three oral presentations and two electronic posters were selected as the best paper candidates.



Neusoft's booth



The congress provided the best opportunity for inter-professional education, the organisers report. 'The 2010 congress included many joint sessions with other medical specialists that provide a unique opportunity for inter-disciplinary education and exchange of professional ideas.'

At the trade fair: Over 80 medical companies showed their products at the medical exhibition held alongside the congress.

Time to socialise: Participants and delegates also attended Congress Presidents' dinner which was enhanced by a demonstration of Persian traditional art, as well as the congress gala dinner. They were also treated to a concert by a traditional Iranian orchestra, and a visit to the Milad tower.

Details: [www.icr2010.ir](http://www.icr2010.ir)



The slide-ready room

The closing ceremony for an event that attracted about 2,500 professionals



# 1st in UK The 1.2 Tesla open vertical high-field MRI system

Three into one will go!

**United Kingdom** – During the opening of the fully renovated InHealth MRI Centre at Mayday Hospital in Croydon, three renowned Harlequin rugby players demonstrated just how ‘open’ the newly installed Oasis 1.2 Tesla high-field open MRI system is.

Rugby players are notably large. This Hitachi system can accommodate patients who cannot fit into a conventional closed bore type of magnet.

‘The bariatric issue is a burgeoning

problem in Europe demanding a radical rethink in MRI design whilst maintaining the necessary image quality’, Hitachi points out. ‘The Oasis provides the widest patient table, largest flex body coil and specific bariatric scanning protocols within an open MR environment meeting the bariatric imaging challenge and reducing rejection rate.’

The design also helps anxious or nervous patients, and those suffering from claustrophobia, because sedation is not

always needed. ‘The 270° angle of vision allows the patient an unobstructed view during the scan for a far more comfortable experience whilst simultaneously giving the clinician a clear view of the examination in progress,’ Hitachi adds.

Referrals to the centre for patients from London and the South-East who suffer claustrophobia have risen significantly since the arrival of Oasis this April.



## A soft tissue probe for in vivo imaging of gynaecological tissue

**UK** – A probe suitable for imaging soft tissue for use with the *VivoSight Multi-Beam* optical coherence tomography (OCT) imaging system has been launched by manufacturer Michelson Diagnostics. The probe enables in vivo imaging of oral and gynaecological tissue.

‘The *VivoSight Multi-Beam* OCT system provides sub-surface cross-sectional images at far higher resolution than is possible with ultrasound, CT or MRI, and much deeper and wider than is possible with confocal microscopy,’ Michelson reports. ‘The new Soft Tissue Probe provides the same unprecedented imaging quality as the Topical Probe, with real time, in vivo images at better than 7.5 µm lateral resolution. The probe is 9 cm long and provides both 2-D and 3-D images over a 5 mm x 5 mm area. For sterile applications, a disposable transparent sheath covers the probe, handle and upper connecting cable.’

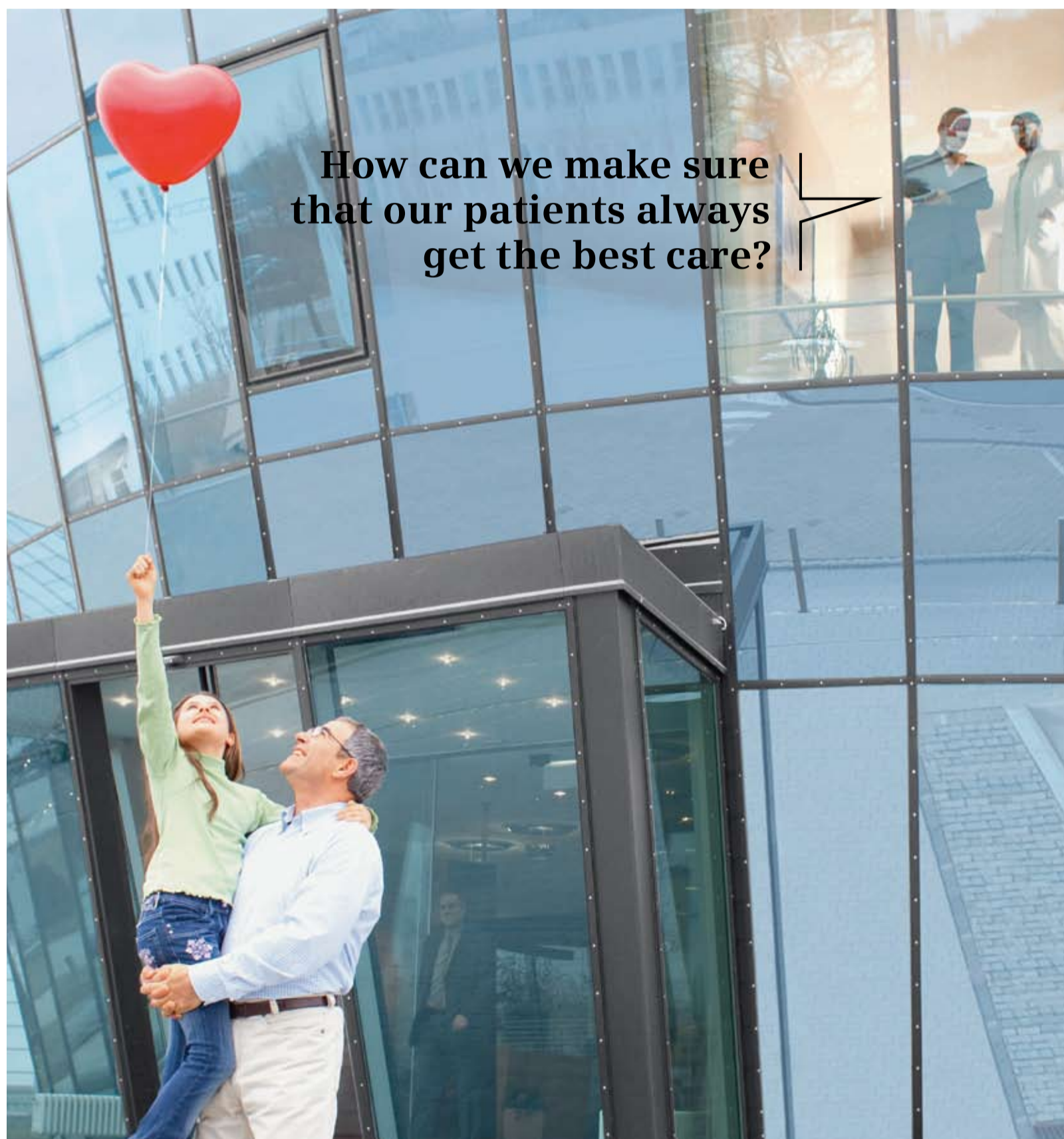
‘The structures of the epithelial layers are exquisitely revealed in



The soft tissue probe

amazing detail,’ said the firm’s CEO Jon Holmes. ‘The new probe promises to be a tremendous aid to clinicians for the diagnosis and treatment of oral and cervical cancers.’

Ex vivo trials on excised oral tissue have shown that *Multi-Beam* OCT can visualize structures such as the epidermal / dermal junction and areas of cellular crowding characteristic of early stage tumours. Michelson’s clinical partners have reported achieving sensitivity of 80% and specificity of 81% for oral cancer diagnosis, from a blinded assessment of OCT images of 125 excised oral lesions. It is expected that in vivo imaging will give even better results and could eliminate the need for a biopsy, the firm adds. ‘The probe will also be suitable for imaging tumour margins prior to surgery.’



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Lawrence Wald



Saskia van Elderen



Mark E Ladd (left) with Tommy Vaughan



Jeanette Schulz-Menger (left) and Thoralf Niendorf

mal MR-scanner. Different research teams, which include basic scientists, mathematicians, engineers and clinical scientists, focus on the development of UHF MRI applications in cardiovascular, neurological and cancer research.

Working with the 7-T whole body MRI scanner includes development of appropriate hardware. 'We received a very well designed MR system. Due to the early stage of the explorations there was limited extra ancillary hardware available - RF-coils suitable for cardiac and body imaging, for example. That's why we set up an environment where we build MR equipment and improve existing hardware,' he explained. Several ultra-high-field centres already have developed prototypes of novel MR-coil hardware and are now in a process of having this hardware certified for clinical applications.

**Barriers against 7-T going clinical**

Dr Franz Schmitt, Director of Ultra-high-field MRI and Collaboration Management in the Siemens AG Healthcare division, the first company delivering a 7-T to Massachusetts General Hospital in 2001, lectured on the remaining barriers for the 7-T to go clinical.

There are still regulatory obstacles. The 7-T is still neither CE certified nor other governing bodies. However, according to Dr Schmitt, in 2003 the FDA agreed to allow UHF MRI up to 7-T, but this is blocked by the regulatory of International Electrotechnical Commission (IEC). The International Commission on Non-Ionising Radiation Protection (ICNIRP), a non-governmental organisation officially recognised by the World Health Organization (WHO), changed its perspective in September 2009 and classified in a guideline the use of up to 8-T as safe in a controlled mode.

A directive of the European Parliament and of the European Council (2004/40/EC), which is supposed to provide measures to protect workers from risks related

to electromagnetic fields (EMF) requires special attention for the daily, routine use of UHF MRI in a clinical environment. In this context, the Alliance for MRI was formed in 2007. This body aims to safeguard the future use of MRI through an EU-wide exemption for use in medical and related research from any exposure limit values set in the Physical Agents 2004/40/EC (EMF) Directive. (Details on the Alliance for MRI are published in our Online Edition [www.european-hospital.com](http://www.european-hospital.com) 01/06/2010).

# The ultra-high-field MRI symposium

## European and North American experts share views in Berlin

Another barrier against 7-T MRI going clinical is currently associated with the large, passively shielded magnets and their overall costs of ownership. Soon, this obstacle will be overcome due to the introduction of actively shielded magnets, Dr Schmitt pointed out. In contrast to the passively shielded magnet, which requires tons of iron for shielding, the actively shielded magnet makes extra iron shielding almost obsolete. For example, a third of the total cost of the 7-T MRI at BUFF was spent on the iron shielding cage that surrounds the magnet.

**Ultra-high-field MRI of the brain**

During the meeting, UHF MRI pioneer Professor Lawrence L Wald, member of the A Martinos Centre for Biomedical Imaging in Charlestown, Massachusetts, USA, and associate Biophysicist at Massachusetts General Hospital, presented his results on depth-resolved laminar analyses of resting-state fluctuation amplitude in high-resolution 7-T in functional MRI (fMRI). In the

past, high spatial resolution MRI was feasible for structural or anatomical imaging only. Achieving a submillimetre spatial resolution in brain fMRI has been elusive as yet, due to the competing constraints of temporal resolution of 2-3s and image quality. Using the sensitivity advantage of 7-T MRI in conjunction with dedicated, home-built RF coils, Prof. Wald and team have been able to produce functional brain images that show subtle intracortical structures (0.5 mm) using 7-T fMRI.

Professor Arno Villringer, Director



The BUFF facility was specially designed for the 7-Tesla MRI installation. The magnet itself weighs 32 tons and is surrounded by a passive iron shield weighing over 350 tons

**UHF MRI in cardiology**

Speaking on 7-T in cardiac imaging, Saskia van Elderen MD of the Department of Radiology, Leiden University Medical Centre (LUMC), The Netherlands, who collaborates with Professor Andrew Webb, said: 'In a direct comparison with lower field strength 3-T increased signal-to-noise ratio, improved contrast-to-noise ratio and improved vessel sharpness were obtained at 7-T within a comparable scan duration. The increase in signal-to-noise ratio can be traded for spatial resolution, which is interesting, for example, in vessel wall imaging, visualising positive outward arterial remodelling one of the earliest stages of atherosclerosis.'

Pioneer in cardiac MRI, Professor Jeanette Schulz-Menger of the Charité Medical University, demonstrated that cardiac chamber quantification at 7-T using 2-D CINE FGRE is feasible and agrees closely with LV parameter derived from 2D CINE SSFP imaging at 1.5. The signal gain at 7-T helped to identify fine, subtle anatomic structures, such as pericardium, mitral and tricuspid valves and their associated papillary muscles, and trabeculae.

Tommy Vaughan of CMMR in Minneapolis, USA, pointed out that 7-T CMR applications become increasingly a research tool, including early explorations into the assessment of regional wall motion using tagging techniques and the assessment of the applicability and efficacy of SSFP imaging techniques at 7-T. According to Prof. Niendorf it should be noted that CMR at 7-T is still in its infancy and needs to continue to be very carefully validated against CMR applications established at 1.5-T and 3-T.

**The future**

In the final session the future perspectives of UHF MRI were assessed. Outstanding in dimension is the project to build an 11.7 Tesla whole body system at NeuroSpin, a centre belonging to the Atomic Energy Commission (CEA) in France. Engineer Christopher J Wiggins PhD explained that the aim of NeuroSpin is to push the current limits of MRI and spectroscopy as far as possible in order to study the central nervous system (Further details: [www.european-hospital.com](http://www.european-hospital.com), a John Brosky report in our Online-Edition. 11/12/2009).

In his lecture, Professor Mark E Ladd, from the Erwin-Hahn-Institute for Magnetic Resonance Imaging in Essen, asked whether 7-T will go clinical - and answered his own question: 'Not yet.' Although technical performance has been demonstrated for particular cases, diagnostic performance preliminary in very small case studies, as yet there has been no demonstration of diagnostic or therapeutic impact, patient outcome, or societal efficacy.

Report: Bettina Döbereiner

Early problems of ultra-high field Magnetic Resonance Imaging (MRI) have been overcome by successful development of adequate hardware. In consequence big efforts have been achieved in structural imaging, as well in functional imaging. Basic scientists and physicians who work in ultra-high-field MRI in Europe and the USA, met at the Berlin Ultra-high-field Facility (BUFF) in the Max Dehlbrück Centre (MDC), Germany, to discuss their findings at the 1st annual symposium.

According to the event organiser, Professor Thoralf Niendorf, head of the facility, the main goal of the symposium was to introduce the BUFF to the international UHF MRI community and to initiate an annual gathering to provide a regular overview of state-of-the-art in UHF MRI, discussions on future directions, foster joint explorations and initiate international collaboration.

Giving an insight into work at the facility (launched in January 2009, and headed by Prof. Niendorf in August that year), he explained that it possesses a 3-T, 7-T whole-body human MR scanner and 9.4-T ani-

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# Ultraviolet light Study proves an invisible weapon can beat MRSA

Our mind was a little conventional regarding infection control measurements. Therefore, when Medixair asked us to test their product in an everyday clinical environment, we didn't really believe it had any impact on hospital infection. The function of Medixair is based on ultraviolet germicidal irradiation and the equipment looks like a mobile air-condition unit. After some negotiations we produced a controlled study that was approved by the ethics committee. It was properly designed with an intervention group and a control group. The intervention room was equipped with a mobile Medixair unit. The control room was without. Both study rooms were treated alike, and patients and environment were screened bacteriologically three times a week.

A significant difference in favour of Medixair appeared very quickly. The difference was surprisingly large; therefore we doubled the study period, but got exactly the same result. During the entire trial



Peder Nielsen

with multiresistant bacteria such as Acinetobacter, ESBL, VRE – and not to forget Clostridium difficile. During the swine flu epidemic, for example, we placed them in the waiting area and the examination room in order to protect patients and staff. In my opinion, 'mobile isolation rooms' may change the way we deal with epidemics because we can 'isolate' many more patients for less cost. Fortunately, many hospitals are taking this into account and air-biology is becoming an important issue.

A few years ago, Dr Peder Bo Nielsen MD FRCPath, Consultant medical microbiologist at Northwick Park Hospital, London, UK, launched a research programme on airborne transmission of nosocomial infections. Until then, so called air-biology held no high priority in infection prevention and control. The prevailing perception was that colonisation and contamination mainly happens due to direct contact with surfaces and/or persons – i.e. hand carried by healthcare workers. A request from a company to test its air-decontamination solution first aroused scepticism, which rapidly changed to amazement and then came conviction. Today, following several years of experience, Dr Nielsen recognises the importance of airborne transmission and the need to include it in any hospital infection and prevention programme. Interviewed by Meike Lerner (EH), he described the significance of his research results

## About Medixair

Medixair is a high energy ultraviolet air steriliser. The unit uses four 25W low pressure mercury UVc lamps that emit germicidal radiation at a peak wavelength at 253,7nm. By arranging the lamps in a close coupled geometric pattern, and employing a slow and controlled airspeed, it is possible to produce exceptionally high germicidal energy levels. Medixair is quiet in operation, economical to operate, portable and easy to install and maintain.

no patients got MRSA in the trial room compared to about 50% in the control room. There could only be one explanation. By taking bacteria out of the air we have protected both patients and the environment. Obviously this raised our interest in air-biology and we did some further tests to prove the risk of MRSA transmission through the air. So we swapped surfaces that nobody every touches like ceilings and, indeed, we found a lot of MRSA in non-touch-areas. That could only mean that MRSA is swirled into the air and then settles down somewhere: on a ceiling, a patient, nurse, in another room. According to the literature, the germs may remain floating in the air for about 30 minutes – quite a long time to 'travel' around. And every time a door, for example, is opened it acts like a fan and the bacteria starts to move again.

Those findings were the reasons to re-think our strategy. Until then we tried to protect the patient and the air from germs by wearing caps, masks and gloves. Now we started cleaning the air to avoid colonisation – with impressive results.

Today, about 30 Medixair are in use in our hospital for a wide range of purposes. Because of the mobility of the system, it is possible to turn every room into an isolation room, which means that we don't move the patient to a special room but bring the isolation room to the patient. We use the Medixair for patients who are colonised with MRSA, and also for any other patient colonised

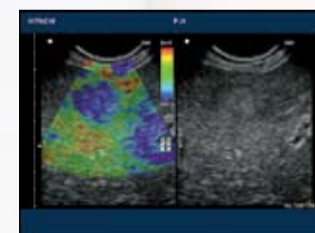
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# TROCAR is on track

European consortium reports first year progress in molecular study of multi-resistant pathogens

The 3-year *Translational Research On Combating Antimicrobial Resistance* (TROCAR)\* project, a consortium of 14 European institutes, has completed its first year of molecular study of high-risk antibiotic-resistant bacteria. 'With expertise ranging from medical microbiology to computational analysis, this network of excellence is on track to identify and target the resistant and multi-resistant bacterial strains that pose the greatest health challenges in Europe,' said Professor Giuseppe Cornaglia (Verona University) Past President of ESCMID. 'The results of this project could provide the scientific foundation for an early warning system such that new high-risk strains can be detected as soon as they begin to circulate in healthcare or community settings.'

In recent years, efforts to control such infections have focused on changing behaviour, e.g. reducing unnecessary antibiotic prescribing and increasing healthcare infection-control measures. Such approaches have resulted in some reassuring effects: better infection-control policies in hospitals have stabilised or decreased rates of infection with MRSA in some European countries.

Nevertheless, MRSA remains a profound clinical and public-health challenge. In addition, many antibi-

otics are losing their effectiveness at an alarming rate due to the emergence of resistant strains of a range of bacteria. Alongside MRSA, the greatest impact is made by vancomycin-resistant enterococci (VRE), Gram-negative bacteria whose resistance to antibiotics results from their ability to produce certain enzymes (extended-spectrum beta-lactamases [ESBL] or metallo-beta-lactamases [MBL]), multidrug-resistant *Pseudomonas aeruginosa*, and multidrug-resistant *Acinetobacter baumannii*. Thus, these pathogens are the focus of TROCAR activity.

The consortium's strategy is comprised of 'work packages' of interdisciplinary research, drawing on expertise in medical microbiology, genomics and proteomics, molecular typing and population genetics, bacterial pathogenicity, and computational analysis.

The initial stage of TROCAR's work has been achieved. 'During this first year of work, we have selected the specific bacterial strains disseminated throughout Europe that pose the most significant challenges to human health in the community and hospital settings,' explained TROCAR coordinator Professor Jordi Vila, TROCAR, at Hospital Clinic, Barcelona. The strains, he added, have been sent to the project partners and Sistemas

Genómicos, a genomics firm, which has started the sequencing process.

TROCAR partner Roland Leclercq, at Université de Caen Basse-Normandie, explained how the isolates destined for gene sequencing were selected in the work package aimed at deciphering the action of vancomycin-resistant *Enterococcus faecium*. 'With our colleagues from Germany (Guido Werner and Wolfgang Witte, Robert Koch Institute, Wernigerode Branch), we have chosen three isolates of *E. faecium*, two from Germany and one from France, all belonging to a clonal complex CC17, a genetic subset of hospital-adapted strains. One was susceptible to antibiotics and was a commensal isolated from a patient's stools; the two others were multiply antibiotic resistant. One was responsible for a sporadic infection and the other caused a large outbreak.'

Genomic and proteomic analysis will now be used to elucidate the parts of these high-risk pathogens' molecular make-up that enable them to spread, to cause severe disease, and to evade destruction by antibiotics. Data from the separate work packages will be brought together on a new bio-informatics platform, which will be used to exploit the genomics information and allow

the rapid identification of emerging high-risk resistant strains in the future. In addition, it is intended that new bio-informatics tools will be developed to allow analysis of the data to detect differences between resistant strains in terms of epidemicity and propensity to persist in the human environment.

Future plans include making data on the distribution and migration

patterns of high-risk antibiotic-resistant pathogens in Europe accessible on the internet.

\* The TROCAR consortium was launched in Barcelona in February 2009, with funding from the European Commission Seventh Framework Programme under the patronage of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID). Details: [www.trocarproject.eu](http://www.trocarproject.eu)

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## MRSA New weapons enter the un-ending war

A decade ago the battle against hospital-acquired MRSA (methicillin-resistant *Staphylococcus aureus* bacterial strain) infections appeared to be lost, or at least without end. However, today, we see very important science-to-business achievements in this field.

In May, for example, two companies – Molecular Detection Inc. (MDI) based in Wayne, Pennsylvania, USA, and Launch Diagnostics Ltd of Longfield, UK – announced an interesting cooperation. Molecular Detection is developing a qualitative real-time PCR (rt-PCR) *in vitro* diagnostic assay called *Detect-Ready*, which helps increase the accuracy, speed, and cost-effectiveness of the direct detection of nasal MRSA infection; Launch Diagnostics is an independent distributor of clinical diagnostic tests and other medical products.

An encouraging aspect of their cooperation is that they signed up an exclusive distribution agreement for MDI's *Detect-Ready* assay that covers the United Kingdom, Republic of Ireland and France (the assay has been already launched in the UK and Ireland), which is just couple of months after signing off another exclusive distribution agreement with Inverness Medical Germany. This March 2010 contract secures distribution of *Detect-Ready* in Germany, Austria, and Switzerland (where the kit had also been launched already).

Several things make me happy about this product. Firstly, *Detect-Ready* kits are compatible with multiple rt-PCR platforms currently in use in clinical laboratories worldwide, including the Roche LightCycler, Qiagen RotorGene and Cepheid SmartCycler, so its usage is just piece of cake.

The assay is supplied as a room temperature-stable, off-the-shelf kit that requires only the addition of patient DNA swab in the reaction tube; results are known three hours later. Secondly, the assay

kits have received the CE mark certification for sales in the EU, and MDI claims that US regulatory clearance is expected by the end of 2010.

Furthermore, nasal cavities are not the only target in MDI's spotlight. The firm is also developing detection kits to determine the presence of various other pathogens in the bloodstream – among them: MRSA, vancomycin-resistant enterococci, *Clostridium difficile*, and cytomegalovirus.

The fact that medical professionals are confronted daily with a still truly serious problem is documented by ongoing efforts to identify the main sources of MRSA infection. Recently, Dutch researchers called for more screening of patients who are repeatedly admitted to different hospitals, because MRSA is mainly spread by those frequently moving between various clinical settings. Professor Hajo Grundmann, from Groningen's University Medical Centre, leads a large multinational clinical study focused on a very interesting aspect of community-acquired MRSA infections – their geographic concentration. Thus the idea to follow-up on the geographical location of different MRSA strains in 450 hospitals across 26 European countries arose.

The conclusion was everything but expected, as Prof. Grundmann said: 'MRSA appears to be spread by patients who ping-pong around between hospitals. These are often frail or elderly people with on-going health problems. The exciting thing is that if we know that MRSA is spread by this core group who are going back and forth between hospitals, we can do something about it and we may ultimately be able to eradicate MRSA.'

You see? Just hope for the best as we approach the new era of scientific/community methods to win this vexing MRSA war once and for all – hopefully. Report: Rostislav Kuklik

## C. difficile Molecular scientists design a very quick cheap test

**United Kingdom** – A small team of researchers at Barts and London School of Medicine and Dentistry in London has developed a rapid, cheap and effective kit to test for the presence of *Clostridium difficile*. And, they report that the new kit costs as little as 50 pence to £1 per test and can deliver results in under an hour, compared to commercial kits that cost up to £25 and in some cases take significantly longer to deliver results.

The kit was designed by Stephen Bustin, Professor of Molecular Science at the Barts and London Hospital, who explained: 'I work in the Academic Surgical Unit at the Royal London Hospital and my clinical colleagues alerted me to the fact that they had a problem with patients being admitted for surgery and contracting CDI. If *C. difficile* appears on the ward, the wards have to be closed down and patients, especially the elderly, are at risk and, in extreme cases, require emergency surgery during which the colon is removed,' he explained, adding: 'There was a real and immediate clinical problem to address for my surgical colleagues.'

Working with a technician and funded by the UK charity Bowel and Cancer Research as well as the Heptagon proof of concept fund, Professor Bustin set about designing an efficient and cost-effective *C. difficile* testing kit. Using a small amount of patient stool sample, the kit utilises real-time quantitative polymerase chain reaction (qPCR) technology to amplify and detect the bacterial DNA, providing results within an hour.

The assay detects the presence



Stephen Bustin

of up to four unique *C. difficile* genes, thus maximising specificity and sensitivity, while minimising problems with false positive results, the professor said.

Most current tests are often antibody based and detect the presence of toxin protein but are not as sensitive as PCR-based assays, while others involve anaerobic cell culture, hence taking several days to produce a result – and they are labour intensive. Commercial PCR kits are available but require specialised instrumentation and can cost £25-30, which becomes expensive particularly if a hospital is looking at some 10,000 assays a year, he pointed out. 'Our idea was to have a test that is better than anything else available at the moment but make it much, much cheaper.'

The resulting kit has achieved this, although Prof. Bustin acknowledges it does require basic laboratory skills to conduct. However, many hospital pathology labs already use qPCR-based assays, so these skills are already available there.

Often a consequence of antibiotic therapy, CDI is the most common and one of the most serious nosocomial illnesses in the UK. Together with MRSA it has

claimed several thousand lives at the peak of outbreaks, although the number of deaths attributed to CDI fell by 29% between 2007 and 2008 to 5,931, after increasing annually since records began in 1999.

Presently, Prof. Bustin's design is seeking a commercial backer, at a time when *C. difficile* is lower down the nosocomial infection agenda, but he is willing to share his assay with other interested hospitals.

Many major London hospitals already test about 9,000 patients a year, but the researchers think many patients were infected prior to hospitalisation; the hope is to use the test on all patients admitted to the colorectal unit at the Royal London Hospital and overturn any resistance to screening patients without symptoms. 'Because the test is so quick and non-invasive,' said Prof. Bustin, 'it won't delay admissions. It will also give us a clearer idea of how much *C. difficile* is out there. It is one of the great killers in our hospitals. It's unacceptable that death rates should continue to be so high in British hospitals.'

The new test is extremely rapid, easy to use, very sensitive and very cheap, he emphasised. 'Therefore it can be used to test patients as often as you like, allowing routine screening of anyone entering a surgical ward, for example, which you would not do at the moment because current tests are expensive, time-intensive or lack sensitivity. Routine testing would have many benefits, not least the potential for preventing outbreaks of CDI.'

Report: Mark Nicholls

# Keeping up with the neighbours

## Dutch-German collaboration aims to beat one-way cross-border nosocomial infections



Ron Hendrix

The border between Germany and the Netherlands in the so-called EUREGIO region is of no particular importance in the daily life of the people who live there. Every day, thousands commute between towns and cities in both countries, to work, shop or even receive medical treatment. The latter, however, presents Dutch hospitals with a problem.

Whilst multi-resistant pathogens have been almost eradicated in the Netherlands, Germany has not yet been able to get halt the spread of, for instance, MRSA. Therefore, patients already treated in Germany present a potential risk.

This was enough for Ron Hendrix MD PhD, at the Laboratory Microbiology in Twente/Achterhoek and Dr Alexander W Friedrich, of the Institute for Hygiene at University Hospital Muenster, to collaborate to find a solution. Their meeting resulted in the *MRSA-net* project. Now successfully completed, the results are in utilised and complemented in the large-scale project *EURSafety Health-net*.

'Within the context of the EUREGIO MRSA-net project, which broadly speaking included the regions Muensterland and Twente, we initially looked at where the real problems were, and we made some surprising discoveries. On the one hand, there are big geographical discrepancies in the spread of MRSA in Germany. In Muensterland the spread was quite small compared to regions such as Berlin, Munich or the Ruhr. On the other hand, talks with the Robert-Koch-Institute showed that the guidelines on the fight against MRSA are identical in both countries. Germany even has a legal framework for their implementation, whilst the guidelines in the Netherlands are only based on agreements,' Ron Hendrix told European Hospital.

The reasons why Germany looks so bad, despite the same prerequisites, are obvious to this expert: 'One significant difference is that Germany – just like many other European countries – has no policy on antibiotics. In the Netherlands we have always prescribed very few antibiotics, and when we do prescribe them we use old style types, such as penicillin. This is very different in the case of our neighbours, where patients demand antibiotics for any cold and doctors then prescribe the very latest generation of drugs available.'

'Apart from the treatment costs involved in this type of strategy the resulting resistancies are not even being considered when it comes to fighting MRSA,' he continued. 'The focus in German hospitals, if any, is on hygiene. The second important difference is that existing guidelines are often simply ignored.'

MRSA-net therefore initially aimed to sensitise hospitals to this subject and to capture and quantify the respective problems through screening procedures. The 44 German hospitals involved have

committed themselves to observing these measures, which are being continuously checked, and they participate in a quality certification scheme.

'The complete results will only be published around the end of this year, but we can already talk about success, because the figures show that the number of MRSA

pathogens grown in blood cultures has decreased significantly,' said Dr Hendrix.

Based on these experiences the EURSafety Health-net was set up towards the end of last year, a project that covers the areas along the entire course of the border as well as Belgium. 340 hospitals are participating.

Dr Hendrix added: 'In the case of EURSafety Health-net an important focus is on antibiotics management, next to hygiene. All hospitals, surgeries or even pharmacies that want to obtain the new certification must commit themselves to reducing the use of antibiotics considerably. Additionally, we don't only focus on MRSA, because

we have found that the same patients are also prone to ESBL or multi-resistant tuberculosis germs. In five years time, when the project finishes, we hope to have eradicated multi-resistant germs in the region just as they have been in the Netherlands – certainly a realistic prospect.'

Report: Meike Lerner

**ETHICON**  
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**Plus**

Antibacterial  
(Polydioxanone)  
Suture



## ONE INFECTION IS ONE TO MANY CONFIDENT CLOSURE WITH A PLUS



Plus SUTURES is an ETHICON family of products coated with the broad spectrum antibacterial agent IRGACARE® MP to prevent bacterial colonization on and around the suture.<sup>1,2,3</sup>  
ETHICON Plus SUTURES: leading the fight against surgical site infection.

**Because one infection is one too many.**

<sup>1</sup> Rothenburger S, Spangler D, Bhende S, Burkely D. In vitro antibacterial evaluation of coated VICRYL Plus antibacterial suture (coated polyglactin 910 with triclosan) using zone of inhibition assays. *Surg Infect (Larchmt)*, 2002, 3:79-87

<sup>2</sup> Ming X, Nichols M, Rothenburger S. In vivo antibacterial efficacy of MONOCRYL Plus Antibacterial Suture (poliglecaprone 25 with triclosan). *Surg Infect (Larchmt)*, 2007, 8:209-213

<sup>3</sup> Ming X, Rothenburger S, Nichols MM. In vivo and in vitro antibacterial efficacy of PDS\* Plus (polydioxanone 25 with triclosan) Suture. *Surg Infect (Larchmt)*, 2008, 9:451-457

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'MRSA will never disappear completely,' says Professor Christian Ruef, 'but ESBL will cause us many problems in various European countries as well as in the USA, Australia and Japan, where enhanced resistance is already more widespread.' As with MRSA, the reasons for multi-resistance are mainly the overuse of antibiotics, along with insufficient hygiene management, particularly hand disinfection. The situation is worsened by the fact that ESBL-producing pathogens are much more prevalent (community-acquired) than MRSA. In addition, as with MRSA, a geographical, north-south divide is distinguishable.

In an international comparison,

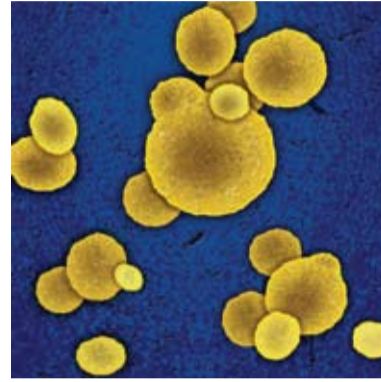
the MRSA situation in Switzerland is relatively stable. With a rate of 5% the prevalence is similarly as low as in Scandinavia and the Netherlands. 'I don't believe that our prevalence figures are good because our hygiene standards are better than those of our neighbours, Germany and France, for instance,' Prof. Ruef points out. 'In fact, I think that we in Switzerland have simply been spared, so far. It's always easier to maintain a low rate of occurrence than to lower a high rate. However, at University Hospital Zurich the development shows that, in the last two years, we've had twice as many ESBL cases than MRSA cases (120:60), unfortunately with an increasing trend.'

# ESBL: A greater danger than MRSA?

**In hospitals, MRSA is considered Public Enemy Number One, and the increase in nosocomial infections, worldwide, has drawn universal attention to this 'superbug'. However, Staphylococcus aureus is not alone – other pathogens are proving their resistance to antibiotics, in the last decade, gram-negative enterobacteria, which form the enzyme extended-spectrum beta-lactimases (ESBL), have joined the nasty high flyers. Produced by some bacteria, these enzymes even destroy the antibiotics effective against MRSA. Professor Christian Ruef, head of Hospital Hygiene at the Clinic for Infectious Diseases and Hospital Hygiene, University Hospital Zurich, Switzerland, has even forecast a shift of prevalence**

Similar to MRSA, enterobacteria are part of the normal bacterial flora of humans, although restricted to the intestine. However, if they spread from there they can lead to respiratory and urinary tract infections, postoperative wound infections and septicaemia (systemic infection). As ESBL pathogens are transferred, just like MRSA, by hand contact, but also through surface contact, they require the same hygiene and isolation procedures as MRSA infections.

What specific dangers do ESBL-producing bacteria present? 'Bacteria of the family enterobacteriaceae, such as Escherichia coli and Klebsiella pneumoniae, which produce extended-spectrum beta-lactimase, are basically no more dangerous than multi-resistant Staphylococcus aureus, with the exception of risk groups such as older patients, where ESBL pathogens can lead to severe infections faster. The difficulty is that ESBL producing, gram-negative bacteria can inactivate almost all beta lactim antibiotics that are effective in the



case of MRSA infection. This means that many ESBL carriers are not only resistant to Cephalosporin but also to antibiotics such as Chinolon. Very often this means that oral treatment is not an option. Outside the hospital the reserve antibiotics cannot be used against ESBL infections because they can only be given in the form of injections or infusions due to their increased toxicity.'

This year, the University Hospital Zurich has experienced a particularly unusual wave of infections with a further pathogen with problem

resistance: 20 cases of Vancomycin-resistant enterococcus (VRE) occurred. 'VRE was previously never a problem in our hospital, which is why this occurrence should be viewed as an epidemiological outbreak,' Prof. Ruef explained.

The transfer of VRE strains from animals to humans has been largely contained through an EU-wide ban on the use of antibiotics in factory farming. For a long time, VRE was therefore all but forgotten. Meanwhile, VRE outbreaks are now occurring more frequently as regionally limited clusters in cities or certain hospitals. Similar to MRSA and ESBL, the treatment spectrum is severely limited. Linezolid is an antibiotic that makes oral VRE treatment possible, as an alternative to intravenous therapy, but this medication is very expensive.

In the future, Prof. Ruef sees a particular problem in the complete resistance of some pathogens. With MRSA and ESBL, as yet this is luckily not the case, he believes. 'There are other examples, such as Acinetobacter, where this broad or complete resistance occurs again and again, and therefore endangers patients' lives enormously. That's why we need to improve the early detection and resistance determination as well as the development of new antibiotics.'

Report: Karoline Laarmann



Christian Ruef



## Technology for Safety and Hygiene

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## Infection outbreaks to be published weekly

**United Kingdom** - A change in political control naturally creates change in the way things are run, and the jaw-jutting 'Get tough' nature of the United Kingdom's new coalition Government is palpable.

For hospitals, one early change relates to data reporting on MRSA bloodstream infections and *C. Difficile*. Up to now, these were published *monthly* by the National Health Service (NHS) Trust; soon they will be published *weekly* – and by the Department of Health (DoH).

The information will appear on *data.gov.uk* (launched by the previous Government to make public access to data easier). Beginning in early July, and starting with the weekly infection figures between April and June, the plan will involve all NHS hospitals in England. Then, there will be just one week between data collection and its publication.

Andrew Lansley, the new Health Secretary, explained that this is an important step towards the Government's broader plans to provide more relevant information to patients, so that they can compare hospitals and healthcare organisations. 'We want to make the large amounts of data that are already collected and used internally in the NHS work for patients, not just managers,' he explained, adding: 'As well as data being published at a hospital trust level, which may include the figures for as many as three different hospital sites, we will disaggregate the data to individual hospitals. In time we will also add other healthcare associated infections, like *E. coli* and MSSA to the list.'

The DoH also intends to examine whether data could be published at department or ward level, whilst still ensuring patient confidentiality.

### Economics

Faced with the country's debts, in its austerity drive the new Government has suggested severe public sector cut backs – involving job losses. Yet, this new weekly demand for infection reports could present a need for additional administrators as well as perhaps software.

Where has the commensurate time come from to analyse the multitude of reports demanded and engendered in the past few decades? The result, in any field or business, is the swelling of administration staff – perhaps, in the case of a hospital, slicing out a piece of the budget that could have been used for patient care.

However, the DoH also intends to check for any existing and unnecessary data collections by hospitals. Ending these just might balance the rise in expenditure – and time – for the weekly publishing of infection data.

Exposure of a hospital's infection levels should be publicised, but surely 12 reports on a hospital in a year are sufficient to indicate any outbreaks and how it has coped with them? Word of an infection travels fast, via posted warnings, patients, visitors and others – a cheaper way for locals to decide on which hospital to attend.

We can only hope the costs for this new, and possibly unnecessary, demand for weekly statistics can, in fact, be covered by eliminating earlier unnecessary demands for statistics.

Report: Brenda Marsh

### UK statistics

From 1993, *C. difficile* and MRSA cases consistently rose, to a peak in 2006.

According to recent figures published by the Office for National Statistics, between 2007 and 2008 the number of death certificates showing *C. difficile* as a contributing factor fell by 29%, to 5,931. Additionally, the number of death certificates mentioning MRSA as a contributing factor fell by 23%, to 1,230.

The emphasis on better hygiene measures and the setting up of hygiene surveillance teams in hospitals (reported by EH in the past) has made a difference, and the downward trend appears to be continuing.

## Dengue infection detection from first fever day

NEW

It's travel time, bringing all the possibilities of fun – as well as disease risk

The dengue virus, for example, is endemic in

124 countries. It is carried and transmitted by mosquitoes. Typically, what follows is a non-fatal febrile illness characterised by fever, muscle pain, headache, and nausea and vomiting lasting 5-7 days. However, the more severe manifestations of the disease – dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS) – can be fatal if not identified and treated in the early stages.

The new *Panbio Dengue Early Rapid* immuno-chromatographic test launched by Alere International\* and designed for use with other dengue serology tests, is reported to help diagnose active dengue infection from the very first day fever appears. Such early diagnosis means therapy and monitoring can begin far sooner, reducing the risk of severe complications such as DHF and DSS.

The manufacturer reports that, in detecting dengue NS1 antigen in serum, the new test can provide a specific diagnosis of dengue infection in 15 minutes following an easy three step procedure. 'This is especially valuable in areas where diagnosis could be confounded by serological cross reactivity. There are four distinct dengue virus serotypes (DEN -1, -2, -3, -4) which are immunologically related and can all cause dengue fever. Although related, the four serotypes do not provide cross-protective immunity against each other, resulting in patients in endemic regions often having more than one infection during their lifetime. The risk of DHF rises substantially with second or subsequent infections, further emphasising the need for early diagnosis that enables early treatment and care.'

\* The new global brand of Inverness Medical, Existing brands, including BinaxNOW, Cholestech LDX, Clearview, Determine, Panbio and Triage, will be changed to the single global brand name, Alere. www.alere.com and www.panbiodengue.com



# Negative pressure wound therapy

Quality in wound care no longer centres only on a successful healing process but is taking a more holistic, patient-orientated approach. Wounds cause pain, impair quality of life, and make treatment far more complex for medical teams. Approaches that facilitate a painless change of dressings and less wound trauma are therefore welcome – and advancing.



Petra Skrobles

In Negative Pressure Wound Therapy (NPWT) a wound is filled with foam, or gauze, and covered with foil and then a pump, or suction system, aspirates wound secretions. The constant or intermittent suction helps to promote the development of granulation tissue faster and more efficiently.

For some time, this promising system was only offered by one provider, and was cost intensive for both in- and out-patient care. However, the market is developing. Two highly specialised international firms – Mölnlycke Health Care, which manufactures wound care and surgical products, and pump manufacturer Medela AG – joined up this spring to introduce in Europe *Avance*, their negative pressure wound treatment system. Petra Skrobles, Marketing Director for Wound Care at Mölnlycke Health Care GmbH, spoke with *EH* about the value and great potential of NPWT

In the future, NPWT is set to become more important through the increased competition in the market, Petra Skrobles pointed out. 'It will become more economical but also more technologically mature. Our *Avance* system, for instance, is characterised by particularly easy and quiet handling. This means significant relief for nurses and also that the patient is not exposed to constant noise.'

'*Avance* is already used in England, Sweden, Germany and the Benelux countries. The feedback has been consistently positive. In Germany, NPWT carried out in a hospital is reimbursed

by medical insurers but if carried out outside the hospital it is not. To convince the operators of the efficiency, on all levels, of NPWT we need more clinical data. So we are working on a study that collects clinical and economic data on NPWT carried out by doctors in surgeries outside hospitals.'

**On what type of wounds is NPWT being used?**

'The primary objective of NPWT wound therapy is initially the preparation of the wound bed for further treatment, e.g. with hydro-active wound dressings, not wound closure. Wound conditioning is achieved through suction, which on the one hand draws together the wound edges and on the other stimulates the growth of new granulation tissue. This type of treatment is used for chronic wounds, soft tissue defects, burns, fixation of skin grafts, but also for abdominal wounds.'

**How long does NPWT treatment take?**

'It depends on the indication as well as the wound's size and depth. Normally it takes around 20 days. The setting of the suction level also depends on the indication. Normally suction between 80 and 120mmHg is applied. After two to three days the dressing is changed



**Advanced NPWT system reduces pain and potential wound trauma during dressing changes**

and the success of therapy, so far, is assessed.'

**How do patients respond to NPWT technology?**

'NPWT is certainly not a painless type of treatment. However, there are various ways to give patients some relief. Suction for instance should be set on an individual basis so that the suction is not unnecessarily high. Although there are general guidelines on NPWT the suction level, as well as the type of suction (constant or intermittent), should be individually adapted to the patient, depending on the clinical picture and indication. For additional comfort, our wound care kits are also available with Mepitel, a wound contact layer with Safetac technology. This reduces pain and the danger of traumatising the wound when changing the dressing.'

- Avance™ benefits**
- High comfort because the system is extremely lightweight and quiet in operation
  - The system is portable and therefore offers higher mobility
  - The navigation menu is clearly laid out: option of user- or patient mode for safe system control
  - It provides quick control of on-screen patient data
  - Canister change (a choice between 300ml or 800ml) involves only a click of a button

**How important is the subject of pain in wound treatment?**

'Above all it's the sense of responsibility among doctors and nurses that is important here. Attitudes towards a patient's pain among hospital staff – specifically among doctors compared with other staff – are bound to be very different. A doctor is more likely to focus on the clinical objective, whereas nurses are more concerned with a patient's well-being. There are also different approaches in different countries and different hospitals: In many hospitals dressings are changed either only by doctors or only by nurses. England is very advanced in this field because there are special tissue viability nurses who are experts trained in the field of pain and wound therapy. Improving the quality of pain therapy for patients has increasingly moved into the forefront over the last few years. We are therefore working on improving patient care not only through our technology but also through changes to the general conditions and framework.'

## MRSA Effective screening can kill several birds with one stone

The MRSA problem has been ignored almost stoically in many European countries for the past 20 years. Thus the number of resistant *Staphylococci* cases exploded from 1% in 1990 around 25% in 2010. However, the recognition that an infection can result in additional hospital costs of up to €10,000 has led to a change in thinking.

The Netherlands, for example, declared war on MRSA with 'search and destroy' strategies at an early stage, confirming the relevance of effective screening measures. European Hospital spoke with Dr Achim Haecker, Product Manager Molecular Diagnostics at Roche Diagnostics GmbH, about the current situation in Germany

Whilst a lot is happening in MRSA screening in German Hospitals, Dr Haecker said, 'There's also a lot of catching up to be done because, since MRSA first became a problem, the pathogen has been able to spread relatively undisturbed. Although Germany has had guidelines on dealing with MRSA, including screening guidelines, which have been mandatory in the context of the Protection against Infection Act since 1999, in the past the implementation has not been very stringent – possibly due to a lack of control mechanisms. Data collected by Roche show that today 70-80% of hospitals carry out screening – but of course means that 20% of hospitals do nothing to detect the pathogen as early as possible.'

'Those establishments that do screen increasingly need to assess the procedures to be used, as speed is a decisive factor. Starting a culture on a blood agar plate remains the method of choice, with very good sensitivity and specificity. Apart from confirming whether a germ is resistant, the culture also provides information on resistance genes, or other pathogenicity factors. The disadvantage of the culture test is that it takes up to three days. Microbiologists considered this too long and therefore developed selective chromogenic media on which only MRSA bacteria grow. A test result is available within 24 – 48 hours, although with comparatively low sensitivity: Only up to 85% of all clinical MRSA samples are detected in this way. The fastest test procedure with good sensitivity currently is the PCR test (Polymerase chain reaction); for example, it takes around 1.5 hours for the Roche LightCycler MRSA Advanced Test\* to generate a result.'

**What is the recommendation for optimum MRSA screening?**

'Many microbiologists recommend the PCR test in combination with a culture,' Dr Haecker explained. 'In countries with a high prevalence it is particularly important to identify and quickly isolate affected patients. As current PCR tests do not deliver information about pathogenicity factors, a culture should then be grown for further specification.'

'This is the most costly option, of course. However, we must not forget an important aspect in this screening debate: The main cost drivers are not those involved in detecting the pathogen but the treatment costs for nosocomial infections and the costs of hygiene management. Looking at nosocomial infections overall, MRSA still dominates, but pathogens such as *C. difficile* and especially ESBL are very much on the advance. Hygiene management that addresses the fight against MRSA also has an effect on these pathogens. Therefore, hospitals that invest in effective screening in fact manage to kill several birds with one stone.'

**Are there any available PCR procedures that can detect all pathogens?**

'These tests are indeed available, such as our LightCycler SeptiFast test. However, due to the costs involved, and length of time required, they are not suitable as screening methods but are mainly used on intensive care wards for the status determination of patients suffering from severe sepsis.'

**Apart from developing new PCR tests, in which direction is the development of procedures to control pathogens and resistance heading?**

'One development, which was also discussed intensively at the last European Microbiology Congress in Vienna (ECCMID), is the introduction of new and fast sequencing technologies. These will play an important role in the diagnosis and treatment of resistant pathogens in the future. Although this is possible even today, it isn't that practical yet – if all genes from a nose swab were to be sequenced this would present us with an almost unmanageable amount of human DNA in which the bacterium would have to be detected with the help of a magnifying glass. Therefore we have to enrich the bacterial DNA beforehand – via PCR test – and then sequence it.'

\* Roche MRSA test LightCycler details: [www.roche.com](http://www.roche.com)

Interview: Meike Lerner



Achim Haecker

## Surgical site infections

**Surgeons increasingly opt for innovative antibacterial coated sutures**

Post-operative wound infection occurs after an estimated 17% of surgical operations – sometimes with devastating consequences for the patient. The list of preventive measures is manifold and long. However, one strategy is increasingly moving into the spotlight: the use of antibacterial coated sutures.

Ethicon Products is at the cutting edge in this field. In our interview, Sandra Rasche (SR), head of this Business Unit at Ethicon Products, described the current and future potential of innovative materials and, critically, their growing acceptance by surgeons

Asked about the role a suture material plays in combating infection, Sandra Rasche said that this is only one factor in the concept of infection prevention – but often a decisive one. 'The use of sutures cannot compensate for a lack of care with hand washing or the use of antibiotics. But, if you take into account that the surface area of abdominal sutures can be the size of a CD cover, the relevance becomes quite obvious. If the use of these innovative materials enables us to lower the infection rate by just a few percentage points this should still be considered a great success, because each infection causes extended suffering for patients. Moreover, postoperative wound infection can have significant economic consequences: According to studies many infections go hand in hand with extended hospital stays; in Germany alone it results in additional treatment costs of several hundred million euros a year.'

In view of those figures, one could assume that the experts were excited about the introduction of the first coated materials... 'Strangely enough, this was initially not the case,' she said. 'Ethicon Products introduced the first coated materials in 2004 – with rather moderate success. This was not because the materials did not have the desired effect, but because the surgeons did not accept them, as initially there were no studies that statistically documented and confirmed problems associated with postoperative wound infection, doctors saw no need for action. This means that, essentially, we had the

solution for a problem which, in their point of view, didn't exist. Meanwhile, this has changed and there are valid figures documenting the frequency of wound infection and its consequences, along with figures on the efficiency of antibacterial-coated sutures.'

'Despite the initial acceptance issues, our strategy to continue our research in this field has paid off: Our product groups Vicryl, Monocryl and PDS (Polydioxanone Suture) cover about 80% of the worldwide market.'

'However, at the point when PDS Plus was introduced the reaction in hospitals had already changed significantly and the change to antiseptic materials had progressed a lot.'

'The relevant professional medical associations now also support the use of the materials, and we carry out joint training sessions and product introductions with them. We will continue to develop new, innovative weapons in the fight against SSI.'



Sandra Rasche

### Antibacterial sutures

#### Vicryl rapid plus

Main indications: Skin and mucosa, episiotomy, oral mucosa, ophthalmology for the conjunctiva, skin closure, indications where fast absorption is useful, circumcision. Stems the growth of: *Methicillin-resistant Staphylococcus aureus* (MRSA), *Methicillin-resistant Staphylococcus epidermidis* (MRSE).

#### Vicryl plus

Main indications: Wound closure for soft tissue, ligatures, general surgery, ophthalmology, peripheral nerve anastomosis and microsurgery (vessels <2mm).

#### Monocryl plus

Main indications: Wound closure for soft tissue, ligatures, skin closure, bowel, peritoneum, uterus.

#### PDS-Plus

Main indications: For soft tissue, fascial closure, paediatric cardiac surgery, microsurgery and ophthalmology, patients with delayed wound healing. Creates a barrier against: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Methicillin-resistant S aureus* (MRSA), *Methicillin-resistant S epidermidis* (MRSE), *Escherichia coli*, *Klebsiella pneumoniae*.

## Intelligent temperature management

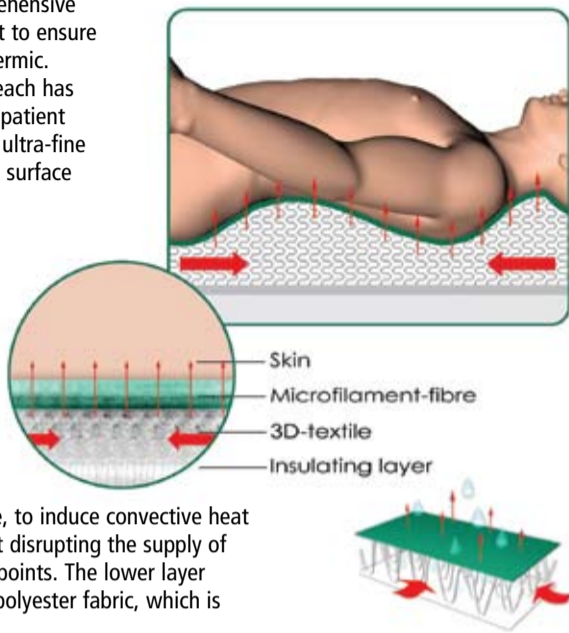
The normal regulation of the core body temperature of a healthy, resting adult human (around 37°C) is affected during surgery, which can lead to an increased rate of wound infections, bleeding and cardiac complications.

The manufacturer of *MoeckWarming System* reusable blankets reports that these provide comprehensive temperature management to ensure patients remain normothermic.

Constructed in layers, each has a green side to cover the patient and this is made from an ultra-fine microfilament textile. The surface absorbs fluids, so surgeons can work immediately with HF instruments without the risk of burns. The range consists of a 3-D textile that facilitates significant pressure relief, the manufacturer reports: 'It is therefore

impermeable to air and moisture.'

Particular patterns produce heat from below and above, using large areas of skin for heat transfer, for all areas of surgery, but this is particularly useful in cardio-thoracic, paediatric and transplant operations.



possible, for the first time, to induce convective heat under the patient without disrupting the supply of warm air on the support points. The lower layer is made from PU coated polyester fabric, which is

## A highly sanitary keyboard with built-in mouse

NEW

### Tests prove far higher resistance to pathogens than rubber or plastic keyboards

That computer keyboards harbour bacteria is well known. Studies have determined that 3,295 germs accumulate per square inch on a standard keyboard. By comparison, a sanitary toilet has 49 germs per square inch.

A study to determine the extent to which computer keyboards could be a repository for three bacteria commonly found in hospitals – methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa* (PSAE) and vancomycin-resistant *Enterococcus faecium* (VRE) – was conducted by Dr Gary Noskin, medical director for healthcare epidemiology and quality at Northwestern

Memorial Hospital, in Chicago, in 2005. The researchers put each bacterium on keyboards and keyboard covers to see how long the bacteria survived. They also typed on the keyboards to see if the bacteria could be transferred to the fingertips.



tal or clinic departments, the importance of keeping computer components as bacteria-free as possible is escalating. However, while rubber keyboards and keyboard covers are the norm in surgical suites, they are not necessarily as commonplace in ICUs, radiology departments, in-patient nurse stations, or patient examination rooms.

To prevent bacteria congregating, Cleankeys, based in Canada, had designed and manufactured a smooth surface wireless keyboard with built-in mouse for dental practices, and this February launched an improved model, aimed for medical departments.

The firm reports that the keyboard, also named Cleankeys, can be kept 99% bacteria free. Models come either with a smooth glass or moulded acrylic surface, with slight indentations for keys. Both surfaces are designed to be thoroughly cleaned in up to 10 seconds using a disposable disinfectant wipe.

**Testing**  
In 2007, Cleankeys was formally evaluated in a study at the Stolley Children's Hospital, Edmonton, to determine how much bacteria was retained after disinfection. A smooth glass keyboard was compared with rubber or plastic keyboards, first being sprayed with a toxic mix of e-coli and MRSA, then allowed to dry, cleaned with a disinfectant wipe and then tested for bacteria. The rubber and plastic keyboards retained 250 bacterial colonies; the Cleankeys keyboard retained only two.

Philip Tierno PhD, author of *The Secret Life of Germs*, recommends that keyboards in a clinical setting be disinfected after each use. However, the time to do this tends to preclude this practice in the majority of clinical settings.

This is the appeal of Cleankeys. It has three pressure settings for use with bare hand or gloved fingers, and a key makes an audible sound when touched. However, the product isn't quite yet perfect. A user must be careful about finger alignment when typing, and typing speed can be slower.

Cleankeys has 21 dealers/distributors covering 16 European countries.  
Report: Kerry Heacox, i.t. Communications

While PSAE could survive only five minutes on a keyboard cover and up to 60 minutes on a keyboard, MRSA and VRE bacteria were far more robust, surviving up to 24 hours after being placed on each surface. Dr Noskin also discovered that the more contact a person had with contaminated keyboards, the more likely the bacteria transmitted to the hands. They measured an increase from 42 to 92% of the time for MRSA, 22 to 50% for VRE, and 9 to 18% for PSAE.

Dr Noskin strongly recommended that anyone using a keyboard in a healthcare setting should wash their hands after each use.

With computers now in use in all hospi-

# The UK's one million undiagnosed diabetics

At the end of June a shocking new estimate was released regarding the number of people unwittingly going about their lives without knowing they are type 2 diabetics – there are just over a million of them. How will the country cope with this discovery and its present diabetic population?

The new figures, from Diabetes Health Intelligence, a strategic programme of Yorkshire and Humber Public Health Observatory, have suggested that, in England alone, 820,000 adults with diabetes are undiagnosed. Based on this model, Diabetes UK – the largest organisation in the country working for diabetics, funding research (over \$6 million in 2010), campaigning and helping diabetics to live with the condition – estimates that the figure rises to just over a million (1.1 million) when applied to the UK, and in the long-term could take the total UK diabetes population to 5.5 million by 2030.

Just think – this number is only 1.7 million short of the entire population of Greater London today. That means a National Health Service (NHS) nightmare of dealing with the equivalent of a large city made up of diabetics.

It's not the only nightmare: Europe's current 646 million people include 55.2 million diabetics. Inevitably, by 2030 those figures will rise to about 659 million people – and they are expected to include 8.1 million diabetics – an increase of 20%.

Diabetes UK CEO Douglas Smallwood said the new UK estimate is 'truly alarming', adding: 'Whilst screening of at risk groups has started, notably through the NHS Health Checks programme, it is clear there needs to be greater emphasis on successful delivery throughout the country.' For what the analysis had shown was that the areas covered by Primary Care Trusts (PCTs) with the highest percentage of diabetes-attributable deaths have a higher than average proportion of over 40-year-olds, and are where they are populated by large numbers of over 40s of Asian and Black origin, who are at higher risk of developing Type 2 diabetes. These PCT areas also have high levels of deprivation compared to trusts with the lowest proportion of deaths. For example, the percentage of diabetes related deaths varied at PCT level from 9% in the more affluent Buckinghamshire area to 17% in the less privileged area of Newham, East London.

Thus the charity also wants to see improved access to health services for the many communities in the UK who, because of their social or ethnic backgrounds, may currently be excluded from mainstream services.

Diabetes UK also stresses the importance of diabetes testing and diabetes awareness programmes being available through a variety of settings, such as pharmacies



Anthony Worrall Thompson with Douglas Smallwood

and local outreach services. 'We urgently also need to improve diabetes prevention and awareness programmes around the country, coupled with vastly improved support for people to change their behaviours,' Douglas Smallwood pointed out. 'Avoidable in so many cases, the Type 2 diabetes epidemic is a clear example of where the new government's rhetoric of tackling health problems through prevention must be turned into action. Failure to act now means a bleak future of spiralling NHS costs and worsening public health.'

Speaking of the country's new government, on hearing the latest diabetes news, its Care Services Minister Paul Burstow said, 'The increase in diabetes is extremely worrying. The Coalition Government has already signalled that public health is a priority. We must help people to tackle the causes of type 2 diabetes through dietary and lifestyle changes. Everyone should ensure they are aware of the symptoms of diabetes, which include thirst, tiredness, unexplained weight loss, passing urine frequently, blurred vision and frequent infection. If you or your child have any of these symptoms you must act immediately and contact your GP for a diabetes test. Delay may be dangerous, especially in children.'

He then pointed to the fact that the PCTs are running risk assessment and management programmes.

### The NHS Health Checks programme

Diabetes UK believes that the Government's NHS Health Checks programme will help to identify more people with Type 2 diabetes.

Introduced in April 2008, the programme is intended to cover 40-70-year-olds in England who have not already been diagnosed with any of four diseases: type 2 diabetes, cardiac, stroke or renal. Those eligible for the health check are receiving, or will receive, invitations to be tested for the risk of the four diseases by their local PCTs. However, the full implementation of the programme cannot be expected for two to three years.

During a 20-30 minute health check, the respondents are first asked questions such as height, weight, sex, ethnicity age, family history, medication taken, and then their BP is checked, a blood sample is taken to check cholesterol, and their BMI is calculated.

A trained professional then gives and explains the results, and advises on health maintenance, any necessary lifestyle adjustments and, if needed, offers medication e.g. to lower BP.

### Costs

The most recent statistics (for 2008) produced by the Yorkshire and Humber Public Health Observatory revealed that one in ten deaths among 20-79-year-olds could be attributed to diabetes. The then statistical projection was that by 2010 this would become one in eight. Imagine, therefore, the millions of deaths attributable to diabetes in 2030 – not to mention healthcare costs. An estimate of the costs of NHS diabetes care is \$9 billion a year – or, taking it down some, one million pounds every hour of the day.

Well, things are bad but, unlike England's footballers in the World Cup, Diabetes UK is not down, but up-beat. 'Following on from the successes of our previous five-year plan, we are now in a strong position to continue developing and responding to changing environments,' Douglas Smallwood has confirmed. And, he adds: 'As the World Cup coincides with Diabetes Week (13-19 June), we thought it would be interesting to see how England's diabetes population compared to the other countries in its group.' The charity revealed that England has the lowest percentage of people with diabetes at 3.6% (2.14 million people), compared with the USA, Slovenia and Algeria – the other countries in its group. Rankings: Bottom of the league: USA - 10.3% of its 26,813,000 population with diabetes; next Algeria - 8.5% of the 1,632,000 population, and then Slovenia with 7.7% of its 153,000 people.

'Although we come out top with the smallest percentage of people with diabetes in the overall population, diabetes is one of the biggest health challenges facing the country today,' he said. 'Type 2 diabetes can be undetected for 10 years or more, meaning 50% of people already have complications by the time they are diagnosed. Furthermore, diabetes is a huge strain on the NHS, which spends \$1 million an hour (or \$9 billion a year) treating the condition.'

Report: Brenda Marsh



# Diabetes management in the Hospital

## Leading expert advises it's absolutely essential

According to **Dr Erhard Siegel**, head of Gastroenterology, Diabetology and Metabolic Diseases at the St Vincenz Hospital, Limburg, Germany, and the first chairman of the Federal Association of Diabetologists in Hospitals, 'Diabetes mellitus as a secondary diagnosis has a significant impact on the course of other diseases, and in-patient stays are unnecessarily prolonged through insufficient treatment. Systemic infections, problems with wound healing, kidney failure necessitating dialysis or increased need for transfusions, to name but a few complications, are directly linked with inappropriately adjusted blood sugar levels in critically ill patients.'

For some time, Dr Siegel has been examining how improved diabetes management in hospital can optimise the quality of care, as well as lead to cost savings. 'The state of diabetological primary care in German hospitals is alarming,' he pointed out. 'In 2008, out of 2,087 hospitals only 250 at most have sufficient diabetes expertise.'

Diabetes mellitus is a lingering disease – for a long time it causes subjectively few complaints or no complaints at all. Despite this, it is life-threatening – especially if undiagnosed, or diagnosed too late. However, although diabetes is the most widespread disease it is often only discovered by accident in a hospital, where many hospital doctors feel that diabetology is the responsibility of colleagues in the out-patient department. So what happens when an in-patient is diagnosed with a secondary diabetes diagnosis?

A study, from 2001-2002, initiated by Dr Siegel in 16 hospitals, showed that in about 12% of in-patients Diabetes mellitus was coded as the primary or secondary diagnosis in the DRG (diagnosis related groups) system.

We can now consult the data analysis carried out by the InEK (Institute for the Hospital

Remuneration System). In 2008, 17.2 million people received in-patient treatment in this country. In 2,100,000 patients (12%) diabetes was coded as a secondary diagnosis and in 215,208 patients (1.3%) it was coded as the primary diagnosis. 'However, these are only the patients who were diagnosed as diabetics – the real number, once the undiagnosed cases are included, is much higher,' said Dr Siegel. 'If no diabetologist is available in the hospital the blood sugar levels are often not monitored and a Diabetes mellitus diagnosis is not made. This means, for the undiagnosed or insufficiently medicated diabetic, that their mortality and morbidity risk increases significantly.'

His suspicion was confirmed by his analysis over several years (Ludwigshafen-Limburger-Diabetes Model). The systematic examination in a maximum care hospital with 45,000 cases (2001-2003) and a specialist clinic with 20,000 cases (2003 – 2005) showed a prevalence of Diabetes mellitus of around 30% and documented complications in

75% of all patients treated in the hospital. Diabetes mellitus (as a secondary diagnosis) is therefore one of the most commonly treated diseases in hospital. However, this secondary diagnosis is only made for 30% of affected patients and follow-on complications are only diagnosed in 10% of patients.

### The economic impact

'We can say that a hospital with 500 beds and a total of 20,000 cases a year can achieve an increase in revenue of between €150,000 and €200,000 for the correct DRG coding for diabetics. The effects of shorter in-patient stays – in the case of diabetes as a primary diagnosis, two days; for secondary diagnosis, one day – need to be added to this,' Dr Siegel said.

Diagnosing, treating and coding: these three steps lead to successful and cost efficient diabetes management. Clearly defined structures and processes that are accessible on the intranet, at all times, in the form of written treatment guidelines are a prerequisite. The implementation of these processes is safeguarded by a diabetologist, a diabetes adviser and specially trained nurses. The 24-hour presence and availability of this diabetes intervention team must be guaranteed.

Interdisciplinary discussions on peri-operative metabolism also play an important role, Dr Siegel added: 'Even among doctors, there's still a perception that diabetes is not really that bad, which is why many surgeons ignore insulination – with catastrophic consequences. It proves there is a need to set up a diabetological consultation service, and the diabetologist in charge needs to be given the cross-

*continued on page 23*



Erhard Siegel

## DIABETES MELLITUS

The world needs to invest in integrated health systems that can diagnose, treat, manage and prevent diabetes

There are about 285 million diabetics worldwide, representing 6.4 % of the adult population (20-79 age group). According to International Diabetes Federation (IDF) figures, the number is expected to reach some 438 million by 2030.

While in the past, Type 2 diabetes was often thought of as a disease of the elderly, there is now a rising trend of Type 2 diabetes in younger age groups. Whereas in Europe the largest numbers of people with diabetes are in the 60-79 age group, in regions as South and Central America, South-East Asia and the Western Pacific, the largest number of diabetics lies in the 40-59 age range, and this age group now numbers 113 million diabetics, representing 46% of the total number.

Additionally, Type 2 diabetes in children is on the rise, a trend clearly linked to an increasing prevalence of obesity, which in turn is associated with changing dietary and lifestyle patterns. The shift to a Westernised lifestyle characterised by, among other things, poor diet and lack of exercise is fast occurring in both developed and developing countries, where it is most common in urban areas. Studies have shown that young Type 2 diabetics run the risk of developing micro- and macrovascular complications at a relatively early age.

The overall annual increase in young Type 1 diabetics is estimated at around 3%. Some 70,000 children under the age of 14 develop Type 1 diabetes annually.

Of the estimated total of approximately 440,000 cases of Type 1 diabetes in children under 14, more

than 20% are in the European Region. Finland, Sweden and Norway have the highest incidence rates for Type 1 diabetes in children.

In addition, diabetes also imposes a large economic burden. Estimates indicate that at least US\$106 billion will be spent on healthcare for diabetes in the European Region in 2010, accounting for 28% of global expenditure. As with the wide variation in diabetes prevalence, the range of spending between countries is expected to be huge, from more than US\$7,000 per person in Luxembourg to under US\$15 per person in Montenegro. Also, more money is expected to be spent on diabetes care for women than for men.

Integrating plans for the prevention of diabetes into national health systems and policy frameworks is an important part of the response. The IDF warns that many health systems worldwide are not yet equipped to handle the extent of the diabetes threat, and that failure to take action will have serious consequences.

'The world needs to invest in integrated health systems that can diagnose, treat, manage and prevent diabetes,' says Professor Nigel Unwin, co-chair of the IDF Diabetes Atlas committee. 'Governments also need to invest in actions outside the formal health sector, particularly in promoting healthier diets and physical activity, to reduce obesity and the risk of Type 2 diabetes. Without effective prevention diabetes will overwhelm health systems and hinder economic growth.'

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## DIABETES

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### The IDF predicts a massive increase in cases

There are more than 285 million diabetics worldwide – a figure predicted to increase to 435 million by 2030.

These figures were forecast by the International Diabetes Federation (IDF) in its *IDF Diabetes Atlas*, published in autumn 2009. 165 countries were included in the statistics.

With a population of 4.3 billion people aged between 20 and 79, the global prevalence of the disease is therefore 6.6%. According to the IDF's calculations, diabetes already costs worldwide healthcare systems about US\$376 billion annually.

The link between obesity and the development of diabetes has long been known. More than 90% of all Type 2 diabetics are overweight. Weight loss lowers blood sugar levels. Therefore treatment as well as preventive measures always begin with body weight control.

Precise scales are a must for all diabetes treatment because they indicate any weight gain at an early stage. In addition, due to their fine graduation such scales immediately indicate any weight loss.

Supporting doctors in the diagnosis and treatment of diabetes, the seca range of scales includes the seca 704, a column scale with a graduation of 100g and a capacity of 250kg. Thus they indicate even the smallest weight loss success, which motivates patients.



Doctors use the seca 704 to measure a patient's weight precisely

## Patient monitoring devices

### Wanted: User-friendly, superior, cheaper systems

In 2009, the continuous glucose monitoring (CGM) market earned manufacturers \$23.5; this is forecast to reach \$52.0 million in 2016, according to a new analysis from Frost and Sullivan (F&S). For the study the markets covered by region are Benelux, Germany, France, Italy, Scandinavia, Spain and the United Kingdom.

The primary factor contributing to the growth is the need for an easy-to-use and patient-friendly glucose-monitoring device, F&S reports: The traditional method of monitoring glucose was difficult and inconvenient for patients. Convenient, patient-friendly and affordable devices that facilitate superior therapy management for diabetes are needed, Akanksha Joshi, F&S Senior Research Analyst, points out.

Western Europe's growing aged population has increased the incidence of fatal diseases (cardiovascular, diabetes, stroke) spurring the need for regular monitoring of patients' glucose levels and pioneering technology at considerably lower rates.

However, CGM is not reimbursed and the per sensor cost is steep: 'The traditional finger-stick method offers glucose monitoring solution at much lower rates and is reimbursed all across Europe,' the F&S analyst points out, but adds: 'While using a CGM the patient has to buy a starter kit and pay for the disposable sensors year-on-year, making the method of treatment more expensive.'

Nonetheless, collaboration with established local companies will help manufacturers to provide effective services and, at the same time, maintain profit margins, the report continues. 'Integration of continuous glucose monitors with insulin pumps will pave way for reimbursement options for manufactures, thus reducing the total cost incurred by patients,' the report reasons. 'To enable the market participants to include such systems in the reimbursable category, significant clinical evidence suggesting that the device is essential for the patient's well-being is required. Moreover, when CGM is integrated with insulin pumps, the product will become reimbursable, as it is likely to fall under the medically essential classification of insurance agencies.'

Report details: <http://www.patientmonitoring.frost.com>

# Type 2 diabetics have elevated risk of 24 types of cancer

Type 2 diabetics run an elevated risk of developing cancer, according to the world's largest study on the combined risk of diabetes and cancer, conducted by scientists at the German Cancer Research Centre (Deutsches Krebsforschungszentrum, DKFZ). The study focused on 24 types of cancer. The effect is most evident for liver cancer and pancreatic cancer. However, by contrast, diabetics have a significantly lower rate of prostate cancer.

Cancer and diabetes: Are the risk factors the same for these two diseases? Or, does diabetes cause body processes that promote the onset or growth of cancer? Why diabetics have a higher rate of cancer than those not affected by this metabolic disorder is still unclear.

To precisely identify the types of cancer in which diabetes plays a role, **Kari Hemminki** of DKFZ collaborated

with colleagues\* in Sweden and the USA in the largest study ever on cancer risks of Type 2 diabetics.

The study included 125,126 Swedish citizens who were hospitalised due to problems associated with Type 2 diabetes. The epidemiologists compared the cancer incidence in these patients with that of the general population in Sweden.

The scale of the study also made it possible to quantify, for the first time, correlations between diabetes and less common types of cancer. The researchers discovered that Type 2 diabetics have an increased risk of developing 24 of the types of cancer studied.

The most significant risk elevation was established for pancreatic and liver cell cancers. The rate of these cancers in Type

2 diabetics is elevated by factor six and 4.25 respectively compared to the general population. The epidemiologists also found the risk of kidney, thyroid, oesophageal, small intestine and nervous system cancers to be more than double.

The study additionally confirmed an observation that suggests that Type 2 diabetics have a significantly lower rate of prostate cancer. This was particularly apparent in diabetics with a family history of the disease. The more family members are affected by diabetes, the lower is the personal prostate cancer risk. 'Right now, we can only speculate about the causes,' Kari Hemminki said. 'Possibly, a lower level of male sex hormones in diabetics may be among the factors responsible for this.'

Could it be that cancer rates in the Type 2 study participants appear to be increased only because their tumours happen to be found earlier as a result of hospital routine diagnostics? To



Kari Hemminki

rule this out, the researchers separately analysed how many cancers had occurred in study participants after one and five years respectively following their hospital stays. Although this revealed a slightly lower risk elevation, the trend was the same.

In industrialised countries, between two and 20% of the population become Type 2 diabetics. Hence, this metabolic disease lies among the greatest challenges for the public healthcare system. Type 2 diabetes, which was once incorrectly termed 'old age diabetes', is characterised by insulin resistance in tissue; i.e. the cells do not take up glucose from the blood upon receipt of an insulin signal.

For the study, the scientists evaluated data reported to a registry following every hospital release in Sweden from 1964 - 2007. These data were combined with the Swedish National Family Cancer Database, a register of all cancer cases in Sweden from 1958. Since the cancer database is linked with a multiple-generation register, it is possible to track cancer cases among parents and siblings of patients.

\* Kari Hemminki, Xinjun Li, Jan Sundquist and Kristina Sundquist: *Risk of Cancer Following Hospitalisation for Type 2 Diabetes. The Oncologist 2010, DOI: 10.1634/theoncologist.2009-0300*



## Insulin analogues for children Will they no longer be free of charge in Germany?

Since February 2008, the Federal Joint Committee (G-BA) has been trying to exclude short acting insulin analogues completely from reimbursement by the statutory medical insurers. Why? Insulin analogues are 30% more expensive than human insulin.

The G-BA sets guidelines for the list of all the services and products to be covered by the statutory medical insurers (GKV) and therefore decides what services will be reimbursed through the insurers. However, in May 2008, the Federal Ministry of Health (BMG) objected to the decision not to reimburse insulin analogues and instructed that the insurers had to reimburse these insulin preparations for Type 1 diabetics up to the age of 18, despite the higher costs involved.

The Federal Ministry reasoned that with the additional cost of 50 cents daily the savings potential of €2.4 million for the G-BA was comparatively small.

This was a great victory for young diabetics who will particularly benefit from treatment with short acting insulin analogues and the added flexibility this offers for their daily routine. Due to the shortened interval between injecting and eating, activities such as sport and play can be carried out more spontaneously. Additionally, the fast correction of blood sugar levels reduces the development of severe and expensive complications and secondary diseases

Nonetheless, it didn't take long for a counter attack. Within the same year, the G-BA instructed the independent Institute for Quality and Efficiency in Health Care (IQWiG) to check exactly what benefits the treatment with short acting insulin analogues for Type 1 diabetes has particularly for children

and adolescents. The Institute stated that, due to a lack of available data – in particular the lack of long-term studies – no proof for an additional benefit could be found. Therefore, in February 2010, the G-BA concluded that the desired treatment objective could be achieved just as functionally – but more cost effectively with human insulin. Put simply: In future, more than 50% of the 25,000 children with Type 1 diabetes will have to switch to treatment with human insulin, or their parents will have to pay for insulin analogues themselves.

A step backward, rather than progress, agreed experts countrywide. Professor Thomas Danne, President of the German Diabetes Association (DDG), said: 'Blindness, kidney failure, premature stroke – these risks had been significantly lowered through improved treatment with short acting insulin analogues. To think that these therapeutic agents might now become unattainable for many children is rather scary.'

In all highly industrialised countries, short acting insulin analogues have been recommended for children, adolescents and those with insulin pumps by the welfare systems, as well as specialist medical and scientific associations, and they are reimbursable.

In May, the DDG and the German Association for Diabetes Education and Counselling Professions (VDBD) therefore petitioned in the German Bundestag (Federal Parliament) for the medical insurers to continue reimbursing the costs of this treatment.

A decision has not yet been reached.

Report: Karoline Laarmann

## Insulin without patent protection



Ursula Rinas

A new method to produce insulin cheaply has been developed by researchers at the Helmholtz-Centre for Infection Research (HZI) in Braunschweig, in a German-Indo collaboration. The group's results are published in the open access online research magazine *Microbial Cell Factories*. The data is freely accessible by anyone and is not subject to patent law.

The researchers wanted to develop a new procedure to increase the yield of an insulin precursor from which the actual insulin can be obtained, and in this way reduce costs.

They found the yeast *Pichia pastoris* and modified the cells so that they produce the building block for insulin while growing on a special medium.

The results were highly gratifying: 'With our procedure, *Pichia pastoris* delivers high yields - twice as much as known before. Already, with few cells, it is possible to produce a lot of the insulin precursor,' said Ursula Rinas, of the HZI.

In the early 1980s, insulin was the first recombinant product approved by the FDA for human application. Today, human insulin is produced as recombinant

protein, using two major routes. One involves the production of the insulin precursor using the bacterium *Escherichia coli* as expression host with complex subsequent isolation, solubilisation and refolding procedures.

The other route involves the well-known baker's yeast *Saccharomyces cerevisiae*. The advantage of the latter route lies in the secretion of a soluble insulin precursor into the culture supernatant, making it easier for isolation and chemical modification. The newly described method from Ursula Rinas and team also uses this route.

The isolation of the precursor from the culture supernatant is only followed by enzymatic finishing. Insulin produced with this new method can be used normally and is identical to human insulin.

\* Original article: *Application of simple fed-batch technique to high-level secretory production of insulin precursor using Pichia pastoris with subsequent purification and conversion to human insulin*. Authors: Gurrankonda C, Polez S, Skoko N, Adnan A, Gabel T, Chugh D, Swaminathan S, Khanna N, Tsiminetzky S, Rinas U. *Microb Cell Fact.* 2010 May 12;9(1):31. [Epub ahead of print]

# Achieving HbA1c target values

**An adequate blood glucose level (4–7 mmol/l) is important not only for a diabetic's daily well-being but also to prevent diabetes-related illnesses. HbA1c is the central marker to evaluate the success of diabetes management. But HbA1c measurement has a crucial limitation: current blood glucose fluctuations are not taken into consideration. However, the recognition of steep post-prandial blood glucose increases is important to prevent extreme phases of hypo- and hyperglycaemia.**

Intermittent regular self-monitoring of blood glucose (SMBG) helps patients with Type 2 diabetes to achieve the desired HbA1c target value and catch and counteract glucose fluctuations. Moreover, the guidelines *Self-Monitoring of Blood Glucose in Noninsulin-Treated Type 2 Diabetes* (pub. 2009, by the International Diabetes Federation), confirm that even Type 2 diabetics who do not take insulin benefit from SMBG. This is a remarkable signal because, so far, decreasing HbA1c has not been considered clinically relevant for this group.

According to Professor Oliver Schnell, Executive Member of the Managing Board and Head of the Department of Diabetes and Cardiovascular Disease, Diabetes Research Institute, Munich, therapy adjustment for Type 2 diabetes should focus on blood glucose measurement rather than on HbA1c, no matter whether the patient takes insulin or not. 'Glucose fluctuations, average pre-prandial, post-prandial and nocturnal blood glucose levels, decrease with intermittent SMBG,' he adds.

Speaking at the 45th annual meeting of the German Diabetes Society, held in Stuttgart, Prof.

## Diabetes management in the hospital

*continued from page 21*

departmental decision-making powers on all diabetes treatment. This means it needs to be in a position, at all times, to check and adjust the blood sugar levels of all patients on all wards.'

Even at the stage where a patient is admitted to the ward there should be general screening by blood sugar testing, and these metabolic test results then transmitted from the laboratory to the ward and the diabetologist's work station. If needed, the diabetologist informs the nursing staff on the wards about all the cases identified a diabetic. The implementation of dose adjustments and treatment documentation is carried out by trained nurses, using standardised forms. 'Diabetology has developed into an interdisciplinary department required across the wards, similar to the fields of radiology and clinical chemistry. It operates almost like a service centre. This is the only way to mobilise resources, save costs and ensure revenues,' Dr Siegel concludes.

Schnell presented promising results of the *Accu-Chek 360° View* study, which looked at structured blood glucose measurement.

522 non-insulin using Type 2 diabetics (HbA1c  $\geq$  7.5%) participated in the prospective, cluster-randomised study, conducted for one year at 37 sites in the USA. Patients in the intervention group received in-depth training on the use of SMBG data. Therapy adjustments were based on quarterly tests (seven

measurements in three consecutive days). However, in the control group HbA1c changes were the prime target parameter.

'While HbA1c had been similar in both groups at the outset of the study, already in the first six months the HbA1c value in the intervention group was 0.35% lower than in the control group,' Prof. Schnell said. Treatment modifications and lifestyle changes were much more frequent in the intervention group (over 80%

of the patients). 'Best outcomes were achieved in the adherent intervention group: the patients who recorded their daily blood glucose levels, who were physically active or changed their nutrition, had HbA1c values that were 0.43% lower than those in the control group.'

Further, SMBG seems to positively impact on diabetes-related emotional stress, the professor emphasised. 'The concern that SMBG exacerbates depression



Oliver Schnell

symptoms and emotional stress is entirely unfounded. The more responsibility diabetes patients are given in their disease management, and the more they learn about their disease, the better they handle it.'  
Report: Karoline Laarmann



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# Postprandial blood glucose

The daily management of diabetes mellitus is a complex interaction between blood glucose measuring, lifestyle aspects and drug therapy.

Large epidemiological trials such as UKPDS (United Kingdom Diabetes Prospective Study) have shown that an optimal blood glucose adjustment has beneficial long-term effects on type-2 diabetics' risk of micro- and macrovascular secondary complications. But, while in the past glycated haemoglobin (HbA<sub>1c</sub>) combined with fasting plasma glucose were considered the most important target values to achieve optimal glycaemic control, newer insights have shown that postprandial blood glucose (PBG) plays an equally – if not greater – role in diabetes therapy. In 2007, the International Diabetes Federation (IDF) launched the 'Guideline for Management of Post meal Glucose', which emphasises that diabetics should have their blood glucose levels closely monitored after meals in order to optimise diabetes control and reduce the risk of complications, particularly cardiovascular disease.

However, the huge importance of PBG for the decrease of micro- and macrovascular complications in diabetes is still underestimated, said Antonio Ceriello MD, Head of the Research Department on 'Diabetes and Cardiovascular Disease' at the Institut d'Investigacions Biomèdiques, August Pi i Sunyer (IDIBAPS), in Barcelona, and Chairman of the IDF Post meal Glucose Guideline Committee, during an interview with Daniela Zimmermann (EH)

**F**ocusing on the importance of PBG, Dr Ceriello made two specific points: 'First, postprandial glucose might be an independent risk factor for cardiovascular disease, even in patients suffering from impaired glucose tolerance also known as pre-diabetes. This assumption

is still controversially discussed because, while there are many epidemiological studies supporting this concept, by now the results of intervention trials are still controversial. Secondly, it is clinically proved that reducing postprandial hyperglycaemia helps to achieve the optimal HbA<sub>1c</sub>

target value (7%). Moreover, a growing number of studies suggest that to reduce post-meal plasma glucose excursions contributes to the reduction of 'glucose variability', an emerging risk factor for diabetic complications and the worst prognosis in the critical care setting.

## PBG guidelines must change

'Our current IDF recommendation says that two-hour post-meal plasma glucose should not exceed 7.8 mmol/l (140 mg/dl) – as long as hypoglycaemia is avoided – which is the normal glucose tolerance in non-diabetics. However, it is now recognised that the blood glucose peak is between 1 and 1½ hours, so we will have to narrow the time frame down in future guidelines.

## Post-meal glucose and cardiovascular diseases

'Insulin is a peptide hormone of vital importance, but too much of a good thing can lead to overkill, which is often true for type-2 diabetics having a decreased sensitivity to insulin action and producing too much insulin that can't be exploited by the body. Furthermore, type-2 diabetics suffer an insulin resistance. Consequently, when a diabetic eats, the glucose stays in the blood plasma, where it causes great damage. The condition of high glucose concentration in the blood induces high releases of free radicals (oxidative stress), which are an important trigger for cardiovascular disease. These arteriosclerotic vessel damages, and inflammations caused by free radi-



Antonio Ceriello

cals, increase the risk for severe circulation disturbance. Therefore, diabetes is the reason for thousands of myocardial infarctions and strokes, as well as foot ulcers, amputations, blindness and nephropathies.

## Hospital staff awareness

'We have to differentiate between the intensive care unit (ICU) and other wards. The ICU staff is well educated to monitor metabolic and other parameters continuously and they are also trained to react quickly in a critical situation. But, as soon as a patient is moved from ICU to another department the staff's diabetes knowledge decreases. So awareness of glucose variability and hyperglycaemia definitely must be improved – because normalising glycaemia can enormously improve prognosis for patients, in every medical field.

# Self-monitoring of blood glucose

## Information/motivation/behavioural skills model highlights why some diabetics fail to utilise SMBG



**A**round 75% of adult Type 1 and Type 2 diabetics say they believe they know what their blood sugar levels are, without testing, according to data presented at the American Diabetes Association 70th Scientific Sessions. These results are important to consider because self-monitoring with a blood glucose meter is essential for people with diabetes to obtain accurate blood glucose results that guide adjustments to meal planning, exercise and, most importantly for insulin users, to dose their insulin accurately. It is one of a number of key findings from a study representing the first-ever use of the well-established IMB (information-motivation-behavioural skills) model of health behaviour practice to understand barriers to self-monitoring of blood glucose (SMBG) among Type 1 and Type 2 diabetics.

Bayer Diabetes Care undertook the study to identify basic social and psychological factors that might be related to SMBG utilisation in individuals with Type 1 or Type 2

diabetes and to understand better why some patients have difficulty adhering to SMBG as recommended by their healthcare providers. Another study objective was to determine whether the IMB model, which has been applied effectively in several health behaviour domains, might be effective in helping to understand and promote adherence to SMBG. The study was conducted by a co-developer of the IMB model, Dr William Fisher, Distinguished University Professor in the Department of Psychology and the Department of Obstetrics and Gynaecology, University of Western Ontario in London, Canada.

The findings revealed substantial information gaps, motivational obstacles and behavioural skills limitations that hamper SMBG adherence. Additionally, they suggest that an IMB skills model for understanding SMBG may be conceptually and empirically worthwhile and might provide a basis for supportive educational and clinical interventions to assist individuals with diabetes to adhere to SMBG recommendations.



'There is a considerable amount of medical literature about adherence in diabetes, and a wide range of interventions have been shown to have a positive effect on knowledge, frequency, and accuracy of SMBG,' Dr Fisher said. 'However, maintaining change in SMBG over time has been variable and may be dependent upon regular reinforcement. What's been lacking is a well-integrated behavioural science model of factors that influence SMBG adherence. We are gratified to see that the IMB for understanding and promoting health behaviour change, that has worked well in a number of areas, including the prediction and promotion of safer sexual behaviour, medication adherence, and other areas, has also provided evidence of utility in understanding SMBG in diabetes.'

According to the IMB model, information about SMBG that is directly translatable into SMBG adherence and appropriate glycaemic control action based on blood glucose results, motivation to act on this information, and behavioural skills for acting

effectively, are the fundamental determinants of SMBG adherence. Well-informed and well-motivated individuals will apply their behavioural skills to affect adherence to SMBG over the long run. Health outcomes of SMBG form a feedback loop that can strengthen or weaken SMBG skills, and moderating factors in an individual's environment – e.g. competing demands from family and work – may also influence a person's ability to engage in SMBG.

Dr Fisher presented the study in a poster, 'Understanding Self-Monitoring of Blood Glucose: An Information-Motivation-Behavioural Skills Analysis' at the 70th Scientific Sessions of the American Diabetes Association ADA in Orlando, this June. The poster was also highlighted during the ADA's first ever guided audio poster tour – a new and innovative session added this year.

## Additional Findings

A substantial number of patients in the analysis reported information deficits with respect to SMBG. In a research sample of 416 adult Type 1 or Type 2 diabetics, 46% and 53%, respectively, did not know that they should test after meals, and 21% and 40% did not know how to look for patterns in blood glucose readings and, as noted above, 75% believe they don't need to test because they can 'tell' without testing what their blood glucose levels are.

Motivational obstacles to testing reported by adults with Type 1 and Type 2 included: reports that testing constantly reminds them that they have diabetes (45-53% respectively), is painful (34-35%),

frustrating (26-25%), and time consuming (25%, 25%).

Behavioural skills limitations reported include difficulty testing without others knowing they are testing (29%, 20% Type 1, Type 2 respectively), difficulty downloading information from their blood sugar meter (27%, 24%), difficulty testing without too much pain (21%, 22%), and difficulty remembering to test (17%, 27%).

Importantly, findings from this research show a significant relationship between the presence of SMBG information gaps, SMBG motivational obstacles, and SMBG behavioural skills limitations with reported frequency of SMBG for individuals with Type 1 and Type 2 diabetes.

Speaking about the study results, Dr David Simmons, Chief Medical Officer for Bayer Diabetes Care said, 'The depth of understanding of information gaps, motivational obstacles and behavioural skills limitations has helped us identify areas of patient education, professional education and development to improve products and services that Bayer can provide to customers.'

## Study Design

The current research applied the information-motivation-behavioural skills model of health behaviour to identify correlates of frequency and adherence to recommended frequency of self-monitoring of blood glucose in a sample of 426 adults with Type 1 and Type 2 diabetes (Type 1=208 and Type 2=218). Participants were enrolled in the Chronic Illness Panel of Harris Interactive and completed the survey on line. Thirty-five SMBG information questions were rated on a 5-point like scale. Twenty-five SMBG motivation items were queried on 5-point and 7-point scales and 34 SMBG

# Burnout prevention in the ICU

Special coaching could significantly improve self-perception as well as organisational and structural issues

'PBG is, of course, part of this strategy. In 2009, the American Diabetes Association (ADA), in conjunction with the American Heart Association (AHA), published guidelines concerning *Diabetes Care in the Hospital* to optimise diabetic control in a clinical environment.'

## Postprandial hyperglycaemia avoidance

'Besides physical exercise, healthy nutrition with a low glycaemic load, and pharmacological treatment with drugs that lower PBG, self-monitoring blood glucose (SMBG) is the most important strategy for successful diabetes management. SMBG gives a direct feedback to the diabetic and the doctor who takes care of him and is therefore the key element to adjust therapy if necessary.'

'Today, SMBG is fortunately simplified by modern meters and electronic diabetes management programmes. Another important tool is the digital diabetes logbook to evaluate data over a longer period of time or compare the influence of different external factors on the metabolism in real-time.'

'Diabetes is a chronic disease that demands a great deal of self-responsibility from the patient and a continuous control from the physician. But a keen metabolic control pays off.'

behavioural skills items were rated on a 5-point scale. This was a cross-sectional study, which is a study done at one point in time, not over the course of time, and can measure the distribution and current relationships of characteristics of interest in a defined population.

Respondents who indicated strong disagreement, disagreement, or neutral responses to correct information, or strong agreement, agreement, or neutral responses to incorrect SMBG information were considered 'uninformed'. Motivational items evaluating attitudes to personal performance of SMBG were assessed on a 5-point or 7-point scale and respondents on the negative side of the scale were coded as unmotivated. On the SMBG behavioural skills scales, those who responded on the very difficult or difficult side of the scale were coded as unskilled.

Correlational analyses were conducted to assess the relationship between SMBG information, motivation and behavioural skills with average testing frequency. In both Type 1 and Type 2 diabetes, all three correlated with testing frequency, with stronger correlations seen in the Type 1 population.

Significant greater limitations, with respect to SMBG information and SMBG motivation ( $P < 0.05$ ), were reported among individuals with Type 2 compared to Type 1 diabetes. Item selection procedures that resulted in formation of internally consistent scales assessing the SMBG information, motivation, and behavioural skills were reported (alphas  $> 0.80$ ), and the pattern of significant relationships among SMBG information, motivation, behavioural skills, and frequency of SMBG) in the samples of individuals with Type 1 and Type 2 diabetes were reported as well.

Full article: [www.BayNews.BAYER.DE/BayNews/BayNews.nsf/id/2010-0339-e](http://www.BayNews.BAYER.DE/BayNews/BayNews.nsf/id/2010-0339-e)

**Austria** - 'In intensive medicine, burnout has a major impact on the quality of care,' says Professor Wolfgang Lalouschek, Medical Director of The Tree Health Care Centre in Vienna and Director of *Medical Coaching*, a consulting institute. For example, in intensive care units (ICUs) where the staff suffers burnout, statistics indicate that patients remain longer in an artificial coma than in ICUs that are more or less free of burnout. 'Obviously, that does not happen consciously,' Prof. Lalouschek emphasises. 'It's rather the accumulation of small decisions that lead to measurably poorer outcomes.'

The clinical staff is particularly at risk of burnout. Several studies conducted in Western countries agree that 20% of physicians and caregivers manifest burnout symptoms and about 50% are considered vulnerable. Personal disposition and the occupational environment influence individual burnout risk. Emotional and physical exhaustion, negative attitudes towards patients and colleagues, as well as reduced

physical and mental working capacity, are the major burnout symptoms. In particular, ICU teams come under extreme stress.

Several ICUs within the Vienna Hospital Association (Wiener Krankenanstaltenverbund), one of Europe's largest healthcare facilities, joined in the pilot project *Burnout Prevention in ICUs*. Several approaches were developed to reduce burnout risk and increase job satisfaction. Since 40 of the 180 volunteers were physicians, the physician-nurse ratio of the study participants roughly corresponded to the actual ratio in the ICUs.

Initially, burnout-relevant factors among physicians and nurses were surveyed. Then, aiming to develop improvements or solutions, the participants underwent 12-18 months of systemic coaching, either in a team or individually. Systemic coaching is a person-centred and solution-oriented approach that focuses on the professional role. The coach does not offer direct or preconceived solutions, but helps the person being coached to formulate goals and develop solutions.



Wolfgang Lalouschek

In the Viennese pilot study, the coaching phase has largely been completed and results are now being evaluated. According to Prof. Lalouschek (who led the project) the coaching showed 'significant improvements compared to the previous situation, be it in terms of individual self-perception, or organisational and structural issues'.

Quality of work, work and information flows as well as leadership markedly improved during the coaching phase. The rounds focus more on interdisciplinary cooperation and are better planned, information flows are clearly defined and coordination with other wards and departments is improved, Prof. Lalouschek reports,

adding: 'Contradicting orders and information deficits were significantly reduced while the social climate and the subjective quality of work have improved.'

Additional results:

- The expected high level of burnout among ICU staff was confirmed
- However, the clinical staff are highly motivated and dedicated
- The staff are highly prepared to engage in additional training and to initiate improvements
- Ethical considerations continue to play a major role among ICU staff. 'We saw that the staff is highly motivated to change those things they have the power to change,' Prof. Lalouschek says. All improvements were realised without additional hiring and/or major restructuring, he adds. 'When people feel they are being listened to, and taken seriously, they are incredibly constructive and committed.'

One drawback: Not all the ICU managers participated in the study and, as the professor emphasises: 'The room for manoeuvre is much greater when all hierarchy levels are involved.'

Report: Michael Krassnitzer

## EuroPCR Highlighting rapid advances in MIS on a beating heart

**France** - The landmark achievements in interventional cardiology that are rapidly advancing minimally invasive surgeries (MIS) on a beating heart were demonstrated during a Paris course on revascularisation (EuroPCR), the annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI).

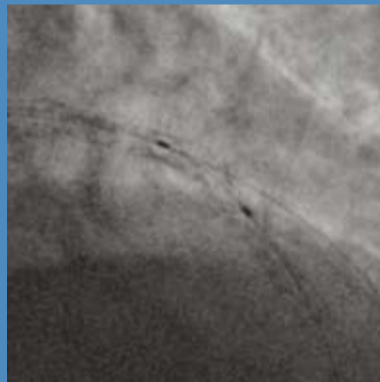
Over the past year, key developments include the emergence of clinical evidence demonstrating that second-generation drug-eluting stents (DES) do, in fact, improve outcomes for patients; that a new measure of the functional severity of coronary blockage, called fractional flow reserve (FFR), has been adopted into practice guidelines, and that transcatheter aortic valve implantation (TAVI) is safe and effective, fueling wider adoption that led to a phenomenal 7,000 procedures in Europe over the past 12 months.

The fast take up of the Xience V DES from Abbott opened a new chapter in interventional cardiology with convincing evidence that improving stents can also improve patient outcomes.

Quickly winning a 50% share in major markets, and displacing former market leaders Boston Science and Cordis/Johnson & Johnson, encourages the host of competitors, which are now bringing even newer and further improved stent platforms toward the market.

'The past year has been very important for innovations in revascularisation,' acknowledged Patrick Serruys, editor of *EuroIntervention*, the official journal of EAPCI.

'There are not less than five different directions being explored by companies pursuing the effects of durable coatings on stents, companies exploring biodegradable coatings, companies not using any coating, totally biodegradable stent structures, and emerging techniques for drug eluting balloons,' he said at the opening press conference.



'It is very appealing with greater choices and innovative technologies, but very challenging as well,' said Serruys, adding that cost-effectiveness may ultimately prove to be the key criteria for the newer generation of stent platforms.

Rebounding at EuroPCR, Cordis unveiled its new Nevo RES stent with a unique structure of reservoirs for sustained release of the sirolimus drug, and announced a new clinical trial for a head-to-head comparison with Xience V.

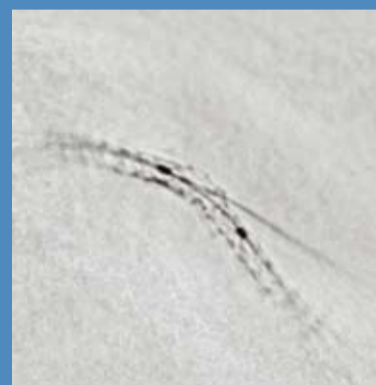
Abbott responded with clinical trial results for a third-generation bioresorbable vascular scaffold that suggests the new device treats a clogged vessel as effectively as a metallic stent, but offers the additional benefit of not leaving a permanent implant behind after the vessel is healed.

With the overwhelming strength of commercial interests in promoting stents, cardiologists have welcomed a new technique for independently determining whether a patient needs a stent in the first place.

During coronary arteriography a small pressure wire is threaded into a coronary artery to measure the range of pressure across a blockage so that the interventionalist can then determine which lesions will benefit from stenting, and which should be treated with medical therapy.

The FFR Angiography for Multivessel Evaluation (FAME) study demonstrated that the technique is cost-beneficial to hospitals and payers by reducing material costs by €550 per patient, lowering average length of hospitalisation by 0.3 days and reducing the total patient treatment cost at 12-months by more than €1,630.

Before and after images using Stentviz, introduced on GE's Innova for cardiovascular fluoroscopy for enhanced visualisation of stent placement 'with the push of a button'



Currently, there are two manufacturers of US Food and Drug Administration (FDA) approved FFR systems: St Jude Medical and Volcano Corporation.

### Capturing change on a cardiac imaging platform

Cécilia Felix, manager of interventional cardiology products at GE Healthcare, told *European Hospital*: 'FFR is now used more than angiograms during PCI in Europe, so we have integrated this data into the monitors used in operating theatres to guide the interventions.'

Both the Volcano and St. Jude systems are compatible with the upgraded GE Mac-Lab XT, which was introduced at EuroPCR.

'Integration to keep pace with new clinical practice does not just mean putting boxes together,' she said, 'but integrating these tools into the clinical workflow as well, which includes an

exchange of patient data and managing medical records.'

The complex dashboard of images and data monitored in real-time by interventionalists operating on a beating heart provides a view of future technologies as well as those already adopted by clinicians. For example, Intravascular Ultrasound (IVUS) is now widely used for an anatomical assessment of lesions or stent placements, and GE has integrated this technology onto the platform.

At EuroPCR, LightLab introduced the first intravascular optical coherence tomography (OCT) imaging system to receive FDA approval, and Cécilia Felix said GE is now looking to integrate this technology into the dashboard. 'If it plays a clinical role, and is accepted by cardiologists, we will take it up and build it into the platform.'

She demonstrated a more advanced clinical feature for 2-D fluoroscopy, which remains the primary reference for cardiac interventions; with this, a 3-D view can be superimposed to support the rapidly growing trend to repair or replace failing heart valves using minimally invasive techniques.

Prior to the procedure, cardiac interventionalists use a 3-D computed tomography (3D-CT) image to assess anatomy and function and plan the intervention, she said. Yet, once the surgeon enters the operating arena these images are left behind and the procedure is performed using 2-D fluoroscopy alone.

At EuroPCR, GE introduced the Innova Vision Technology that overlays the 3D-CT image on the 2-D fluoroscopy, matching the two images with anatomical registration.

Innova Vision includes image stabilisation features, such as ECG-gated display and motion-tracking algorithms, to assure the overlaid images remain precisely matched even with cardiac and respiratory motion.

# COLONIC STENTS

## BUYING TIME FOR SURGERY

By Ajay Bernard Chakraborty MD and Debasish Ghosh FRCS PGCert

In 2006, about 307,432 new cases of colorectal cancer arose in the European Union. The rates varied by a factor of two for women and three for men. The lowest rates were in Greece; the highest in Hungary and the Czech Republic (Fig. 1.1).

The incidence of colorectal cancer is increasing in Europe, particularly in the south and east, where rates were originally lower than in Western Europe.

In the U.K, approximately 34,000 patients are diagnosed with colorectal cancer annually. Left-sided colorectal carcinoma accounts for 56% of all colorectal cancers. Acute left-sided colonic obstruction is most often caused by malignancy in up to 40% of patients and acute colonic obstruction has a high mortality (12%) and morbidity (39%).

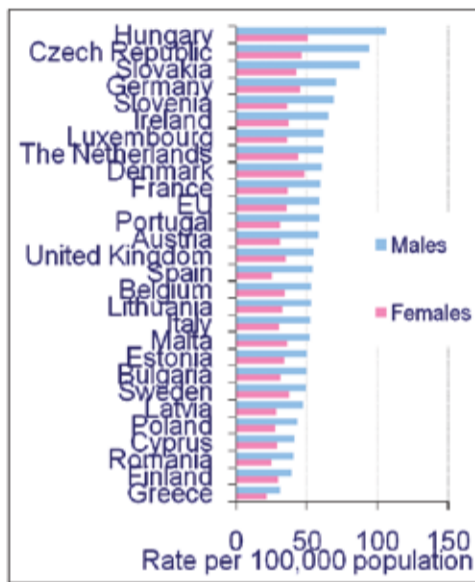


Fig. 1.1: Age-standardised (European) incidence rates, bowel cancer, EU, by sex, 2006 estimates

Left sided tumours present with large bowel obstruction and signs and symptoms include change in bowel habit, absolute constipation, abdominal distension and late vomiting.

Traditional management included fluid resuscitation and emergency laparotomies and ranged from loop colostomies to a Hartmann's and even subtotal colectomies. These interventions have a mortality rate of 15-34% and a morbidity rate of 32-64%. The pitfalls included the unwell patient, advanced age and uncontrolled significant co-morbidities.

A newer approach was to optimise the patient's condition by decompressing the obstruction, staging the disease appropriately, controlling the co-morbid conditions and offering the 'right' patient the 'right' type of intervention – by inserting a stent.

Colonic stents were introduced almost 20 years ago and their first published use came out in 1991. The first stents used in

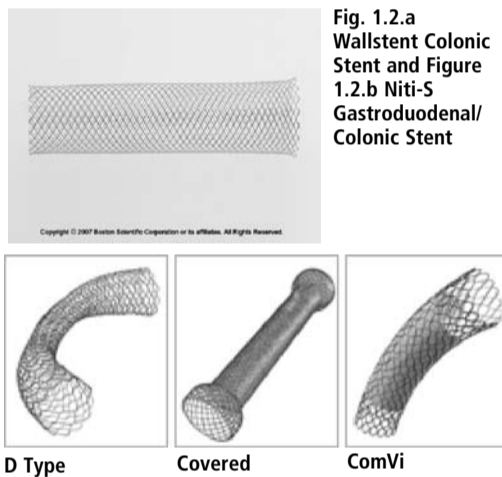


Fig. 1.2.a Wallstent Colonic Stent and Figure 1.2.b Niti-S Gastroduodenal/Colonic Stent

the large bowel were designed for vascular and oesophageal use, but have since been designed specifically for placement in the colon. Colonic stents are self-expanding metal stents.

In theory those patients not eligible for stenting are those with rectal lesions and those lesions before the splenic flexure reasons being tenesmus and difficult bowel prep respectively. But papers and reports have been published of stents being used not just relieving obstruction in malignant left-sided strictures but also those caused by diverticular disease, rectal disease and right-sided colonic obstruction, but these will need further evaluation.

As a rule colonic stents have been used as a 'bridge to surgery' in patients with no significant co-morbidities prior to intervention and no metastatic disease i.e. resectable tumours and as a definitive procedure/palliation in patients with significant co-morbidities, metastatic disease and at high risk of mortality associated with general anaesthetic.

The current stents available are uncovered, but there have been reports on the use of uncovered and covered oesophageal stents in the colon. Various enteral stents are now marketed. The most widely used stents are manufactured in the United States; Ultraflex Precision Colonic Stent System and Wallstent Colonic & Duodenal Endoprosthesis by Boston Scientific/Micro-invasive, and in South Korea, TTS (through the scope) Niti-S Colorectal Stent and Niti-S Colorectal Stent by Taewoong- Medical Co. Ltd.



Fig. 1.3: Colonic stent in-situ relieving obstruction caused by colonic malignancy

Stents can be inserted under fluoroscopic guidance, endoscopic guidance or a combined approach.

Overall technical success rates are generally in excess of 95% with relief of obstructive symptoms in 85%-90% for palliative stenting. In a comprehensive review of 58 publications on colorectal stent publications from 1990 to 2000 stent insertion was successful in 551 of 598 cases (92%).

But not all procedures are without complications, which include perforation, migration, re-obstruction, bleeding and pain. Perforation, the most significant complication, can lead to peritoneal tumour spill and thus can make a potentially curable disease incurable.

However, various studies over the years have compared the use of both colonic stents as a bridge to surgery and as palliation when compared to emergency laparotomies. It may come as no surprise that most papers support the use of colonic stents as the technology and expertise becomes more readily available to smaller district general hospitals. Also, colonic stenting for patients with acute colonic obstruction secondary to a resectable colonic tumour is comparable in cost with surgical options.

The latter has been the case in the district general hospital where we worked. Since 2007, colonic stenting became a more widespread practice. Over the past three years, the General Surgery Department in conjunction with the Gastroenterology Department (in a multi-disciplinary approach) have stented just over 20 patients. Results showed 83% of patients underwent surgery after stenting as a bridge procedure, whereas 17% were unable to undergo surgery due to metastatic disease and thus had stenting as palliation. The major complication encountered was rectal bleeding.

Conclusion: Colonic stents have proved their worth in the emergency management of left-sided bowel obstruction by significantly reducing the mortality and morbidity.

## Updated equipment improves trauma care

A Czech Republic traumatology centre, updated with Trumpf medical technology, has reported quicker and more appropriate responses to planned as well as acute, unforeseeable operations

Treating seriously injured patients is part of daily routine for medical teams at the Orthopaedics and Traumatology Department of the University Hospital in Brno. Up to 2,600 operations a year take place in this department alone, in the second largest Czech clinic. 'With 124 standard beds, 24 intensive care beds and 66 physicians and surgeons in all specialist fields, we cover the needs of a region with a population of around 1.8 million,' explained Professor Michael Mašek, neurosurgeon and head doctor at the Traumatology Centre.

One focal point of the work involves polytrauma patients, i.e. those with critical and/or several injuries. 'To be able to guarantee the best possible emergency

medical care, we need people with the necessary specialised qualifications and, naturally, state-of-the-art medical technology as well,' the professor added.

Among others, the European Union provided the department with support. Thus, in 2009, the Traumatology Centre could invest around 82 million Czech crowns, approx. €3 million, to update emergency room and surgical equipment.

Five Trumpf TruSystem 7500 operating tables as well as a Saturn table system, five iLED surgical lights and ten klinoPORT ceiling pendants were selected and installed.

### High-tech speeds treatments

Speaking of the Trumpf operating tables, Prof. Mašek observed: 'They give us the necessary scope to respond quickly and appropriately to all planned and especially acute, unforeseeable operations.'

To explain this benefit further, Trumpf said that the tables enable extreme and flexible adjustment angles that can be



The modernised surgical unit at Brno

controlled rapidly and intuitively via remote control or touchscreen. The programmable high-speed motors of the TruSystem 7500 guarantee patient positioning with millimetre precision – depending on the requirements of the respective operation. 'This means,' added Prof. Mašek, 'we can now carry out special operating procedures, such as access via the patient's back for pelvic injuries.'

At the Centre, the medical teams and, not least the patients, additionally profit from optimised intra-operative diagnostics.' Trumpf pointed out. 'The TruSystem 7500 carbon tabletop, designed for total body coverage and patients weighing up to 360 kilograms, permits significantly improved X-ray images without irritating artefacts as compared to the previous

solution.' And, the professor added: 'The fact that the operating tabletops can be interchanged safely and smoothly is also an invaluable advancement for us.'

The operating table accessories, e.g. for extension, enlarges the range of surgical disciplines for the team, now making thorax operations possible, among other procedures.

'Thanks to the new investments in state-of-the-art medical technology, we have taken a tremendous leap towards our goal of guaranteeing rapid and stable operative care for all patients,' Prof. Mašek concluded. 'This reduces complications and enables patients quickly to resume a healthy life – thus resulting in an economic advantage for the whole society in the end.'

## ONCOLOGY Tailoring cancer

New biomarkers play a key role in individualised tumour therapy. They are important indicators for pathological processes in the body and for the use of adequate cancer drugs.

In our *European Hospital* interview Professor Celso A Reis, from the Institute of Molecular Pathology and Immunology of the University of Porto (IPATIMUP\*) in Portugal, discussed the current state of clinical use of biomarkers and research in this field

Asked what the forecasts may be regarding biomarkers for cancer diseases, Professor Reis explained that there are two approaches in the use of biomarkers: 'First, it is standard to detect solid tumours and to determine a therapy response. By analysing the presence of a specific receptor in a cancer cell, it can be shown if a patient responds to an inhibitor drug or not. There is already good data supporting this kind of application, but the existing biomarkers are still very limited to specific types of cancer, such as breast, lung or colon. Second, biomarkers can help to identify pre-cancerous conditions. The fact is that the use of biomarkers in an early cancerous state is not yet very popular. A lot of information is not completely standardised in clinics, so it needs to take a further step here.'

### Biomarker research

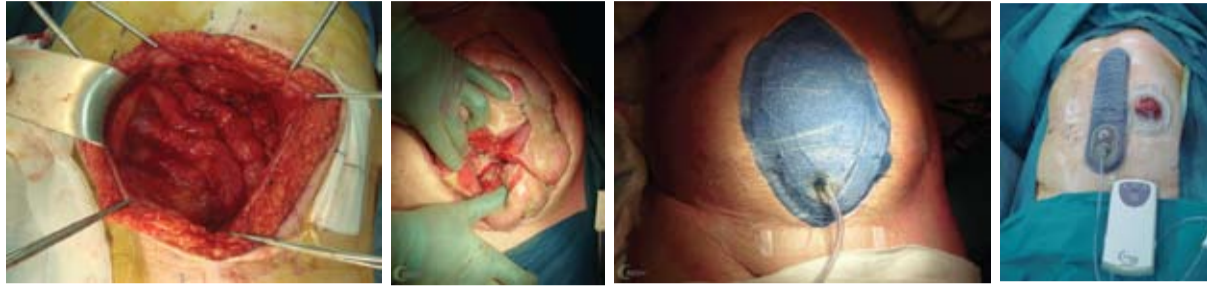
At IPATIMUP the focus is on identifying biomarkers that can improve treatment in patients with gastric



Surgeons aided by enhanced illumination of surgical sites

# Negative pressure wound healing technology

## Many new devices on the way this summer



James Stannard

Despite some uncertainty about how it works, there is a growing consensus that Negative Pressure Wound Therapy (NPWT) – also known as Vacuum Assisted Closure (VAC) – is revolutionising wound care.

Speaking at the first International Surgical Wound Forum, held recently in Amsterdam, surgeons from Europe and the USA predicted the growing use of this innovative technology across the spectrum of wound management.

With a raft of new product launches due this Summer, hospitals across the EU could be freeing expensive ICU time, discharging patients earlier, and sending people with smaller wounds (e.g. diabetic ulcers) back into the community with disposable, iPod-sized, vacuum devices connected to their lesion.

Recent months have also seen a growing enthusiasm for 'prophylactic' use of negative pressure devices to help heal surgically closed incisions before problems such as infections occur. However before prophylactic use becomes widespread, more data are needed on which patients are likely to benefit, says Professor James Stannard, Department

of Orthopaedic Surgery, University of Missouri, USA, and Chair of the ISWF meeting. 'The key is to define which wounds have a high enough incidence of problems to make it worth while intervening prophylactically.'

Prof. Stannard currently restricts 'closed wound' use to high-risk patients, such as brittle diabetics, rheumatoid arthritis patients with thin skin, very obese patients, smokers, some trauma and some older patients.

Recently, he completed a study (in press) that shows a mean half-day saving in time to discharge when such patients are targeted. 'If we save some patients from an infection, multiple surgery, or long term antibiotic use, the advantage is greater. However, if we start intervening on lower-risk patients then the equation will go the other way – and this is going to be expensive.'

At the other end of the wound spectrum – the challenging ICU patient with an open abdomen following laparotomy, severe abdominal infection, intra-abdominal hypertension or abdominal compartment syndrome – there seems little doubt about the benefits of nega-

tive pressure therapy. 'It has revolutionised the treatment of the open abdomen,' said Anne Pullyblank, Consultant Colorectal Surgeon at the North Bristol NHS Trust, UK. 'VAC has massively reduced the time nurses spend changing dressings. It shortens length of time on ITU and improves time to wound healing.'

Peter Laws, Vascular Surgeon at Worthing and Brighton Hospitals, Western Sussex Health Trust, has been using VAC dressing to manage complex diabetic wounds for about five years.

'Typically we revascularise, then debride the tissue and apply a VAC dressing to encourage granulation tissue. Once we have done that we skin graft the wound afterwards,' he said. 'I was initially sceptical about this technology, but I admit to being a convert. We get some great results; reduced wound infection rates and improved time to healing. There is also excellent evidence to suggest that VAC improves the success rates of skin grafts.'

He foresees many more diabetic patients being discharged with portable VAC units. 'I want to push greater use

of VAC therapy in the community because I believe that it reduces costs overall.'

Prof. Stannard, one of the pioneers of negative pressure wound therapy, said that the formal evidence base for this technology is relatively modest, comprising eight truly prospective randomised multi-centre trials. However, he added that more trials are due to be published in 2010.

'For me it was not intuitively obvious that "sucking on a wound" would make it heal faster. Three explanatory mechanisms have been proposed: improved blood flow and angiogenesis, oedema reduction, and the suggestion that applying mechanical stretch to cells causes them to produce factors that help with wound healing.' Prof. Stannard added that, although he had no doubt that negative pressure helps in the conventional setting of a large open wound, he hoped to see more studies published evaluating use in clean closed surgical incisions.

Report: Ian Mason

### Negative pressure wound therapy

How does it work? Vacuum-assisted closure creates local negative pressure over a wound bed to promote healing. A foam dressing is cut to shape and inserted into the wound. This is covered and sealed with self-adhesive film. A vacuum drainage tube is fitted through the film and connected to a vacuum source. Controlled negative pressure is then applied for as long as required.

The dressing effectively turns an open wound into a controlled, closed wound while removing excess fluid from the wound bed to enhance circulation and remove bacteria. As healing progresses the wound edges are gradually drawn together by the dressing hastening wound closure.

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underway in both first-line and adjuvant settings, as well as in other tumour types (lung and prostate cancers).

Commenting on the results, Professor Alexander Eggermont, Erasmus University Medical Centre, Rotterdam, the Netherlands, said that during 25 years of treating melanoma he had never previously seen any melanoma trial with this level of survival benefit.

'To see a trial with this magnitude of difference in patients who already have progressed on chemotherapy was a pleasant surprise. The likelihood that this drug will ultimately be used in first line treatment is now very great.'

Report: Ian Mason

## treatment with biomarkers



Celso Reis

cancer, he explained. 'The problem in this cancer is that initial symptoms are similar to non-malignant disease. So normally, when a person presents

symptoms where he goes to see a doctor, the cancer is already in an advanced stage. One of our major targets therefore is to detect alterations that can be used as a biomarker, such as detecting antibodies that indicate an early oncological disease process. And, hopefully, depending on the kind of marker, even to get information regarding the organ affected. There are other groups in Europe that are collaborating within the same type of research in other organs. We ourselves have collaborations with Germany, Denmark, England and France. I really believe that, depending on the type of studies that will be done in the future, oncologists will decide tumour therapy based on the set of biomarkers that a patient has, so that every treatment is based on each individual molecular profile.

**What kind of molecular methods are used to search for biomarkers?**

'In our lab we detect alterations of glycosylation of proteins of cancer patients. This glycoproteomics strategy may be considered in an early research phase, where we want to discover novel biomarkers. Another strategy is the detection of auto-antibodies. Similarly to

what happens in infectious diseases, our immune system produces an immune response that may lead to production of antibodies directed to antigens of the infecting micro-organism. Our immune system also produces antibodies against small alterations that occur in proteins that are expressed in cancer cells. Our immune system also produces antibodies to such antigens.

**In clinical use, how does the diagnostic test work?**

'Presently, there are few serological assays that detect biomarkers in the serum of a cancer patient. Unfortunately, most of these biomarkers are only used for monitoring therapy, with little application in early diagnosis.

'I foresee that, in the future, the new assays will be based on standard technology. The perfect case would be that the test would be performed during a regular medical check up you do from time to time at your doctor's. This early detection would be very important for the successful therapy for the patient, as well as being economically very beneficial, because it will result in a better treatment outcome, avoiding the complications of oncologic disease progression.'

Interview: Karoline Laarmann

\* IPATIMUP is a private non-profit association of public utility, established in 1989 under the aegis of the University of Porto. Since 2000, IPATIMUP has been an Associated Laboratory of the Ministry of Science and Higher Education.

## Advanced melanoma

### Novel monoclonal antibody success leads Europe and USA to run 'compassionate use' programmes



Caroline Robert

An increase in survival in metastatic melanoma – the cancer with the most rapidly increasing incidence across the EU – has been shown for the first time in a major international study by researchers from across Europe.

The study, a highlight of this year's ASCO (American Society for Clinical Oncology) Congress, was simultaneously published in the *New England Journal of Medicine* (5/6/10. www.nejm.org). The results showed that patients who received a novel monoclonal antibody called ipilimumab lived 34% longer than control patients given gp100 peptide vaccine.

Triallist Dr Caroline Robert, of the Cancer Centre Institut Gustave Roussy, France, reported that, after two years, 22% and 24% of patients in the two ipilimumab arms of the study were alive, compared with 14% in the control arm.

Ipilimumab works by inhibiting cytotoxic T-lymphocyte-associated antigen 4 (CTLA4) a physiological brake on the immune system, Dr Robert explained. 'Releasing' this brake

activates T-cells, which can then attack tumour cells.

'This is the first agent to show a survival benefit in advanced melanoma – a significant number of long-term responders have been observed,' she pointed out. An unusual feature of this antibody treatment is that skin lesions initially can increase in size as they become flooded with T-cells. 'Patients need to be warned that this can happen, because they can be quite alarmed by the sudden increase in tumour size,' said Dr Robert.

Though ipilimumab is not yet licensed, compassionate use programmes have been instigated in both the USA and Europe. Treatment-related adverse events can include gastrointestinal toxicity, hepatotoxicity, endocrinopathy and neuropathy. A management algorithm has been developed. Since implementation of these guidelines there have been no serious problems or treatment-related deaths, Dr Robert said. Ipilimumab trials are

